

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AN ILLINOIS PHYSICAL
THERAPIST CLAIMED
UNALLOWABLE MEDICARE
PART B REIMBURSEMENT FOR
OUTPATIENT THERAPY
SERVICES**

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Office of Inspector General

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EXECUTIVE SUMMARY

An Illinois physical therapist in private practice improperly claimed at least \$634,837 in Medicare reimbursement for physical therapy services.

WHY WE DID THIS REVIEW

In recent years, outpatient physical therapy payments have increased annually with total payments to physical therapists in private practice (therapist) totaling \$1.7 billion in Calendar Year (CY) 2011. Past Office of Inspector General (OIG) reviews have identified claims for outpatient physical therapy services that were not reasonable, medically necessary, or properly documented, and vulnerable for fraud, waste, and abuse. After analyzing Medicare claims data for CY 2011, we selected multiple physical therapists for review, including this therapist located in the State of Illinois. Our analysis indicated that, among other selected criterion, this selected therapist was among the highest Medicare therapy billers in the State of Illinois.

Our objective was to determine whether outpatient physical therapy services provided by an Illinois physical therapist in private practice were paid in accordance with Medicare requirements.

BACKGROUND

Federal regulations provide coverage of Medicare Part B outpatient physical therapy services. For these services to be covered, they must be medically reasonable and necessary, they must be provided in accordance with a plan of care established by a physician or qualified therapist and periodically reviewed by a physician, and the need for such services must be certified by a physician. Medicare Part B also covers outpatient physical therapy services performed by or under the personal supervision of a therapist in private practice. Federal law precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.

HOW WE CONDUCTED THIS REVIEW

Our review covered 4,298 Medicare outpatient physical therapy services totaling \$645,966, provided by a therapist from January 1 through December 31, 2011. A claim consisted of all payments made for a beneficiary on the same date of service.

WHAT WE FOUND

The therapist claimed Medicare reimbursement for outpatient physical therapy claims that did not meet Medicare reimbursement requirements. Specifically, of the 100 claims in our random sample, the therapist improperly claimed Medicare reimbursement on 99 claims, all of which contained more than one deficiency. The therapist properly claimed Medicare reimbursement on the remaining claim.

These deficiencies occurred because the therapist did not have adequate policies and procedures in place to ensure that the therapist billed services that met certain Medicare requirements.

On the basis of our sample results, we estimated that the therapist improperly received at least \$634,837 in Medicare reimbursement for outpatient physical therapy services that did not comply with certain Medicare requirements.

WHAT WE RECOMMEND

We recommend that the therapist:

- refund \$634,837 to the Federal Government and
- establish adequate policies and procedures to ensure that outpatient physical therapy services billed to Medicare are medically necessary, correctly coded, and adequately documented.

THERAPIST'S COMMENTS AND OUR RESPONSE

In written comments on our draft report, the therapist, through his attorneys, disagreed with our findings and recommendations. After reviewing the information provided in the therapist's written comments, we maintain that our findings and recommendations are valid.

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INTRODUCTION

WHY WE DID THIS REVIEW

In recent years, outpatient physical therapy payments have increased annually with total payments to physical therapists in private practice (therapist) totaling \$1.7 billion in Calendar Year (CY) 2011. Prior Office of Inspector General (OIG) reviews have identified claims for outpatient physical therapy services that were not reasonable, medically necessary, or properly documented, and vulnerable for fraud, waste, and abuse. After analyzing Medicare claims data for CY 2011, we selected multiple physical therapists for review, including this therapist located in the State of Illinois. Our analysis indicated that, among other selected criterion, this selected therapist was among the highest Medicare therapy billers in the State of Illinois.

OBJECTIVE

Our objective was to determine whether outpatient physical therapy services provided by an Illinois physical therapist in private practice were paid in accordance with Medicare requirements.

BACKGROUND

The Medicare Program

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

Medicare Part B provides supplementary medical insurance for medical and other health services, including outpatient therapy services. CMS contracts with Medicare contractors to process and pay Part B claims.

Medicare Outpatient Physical Therapy Services

Medicare Part B provides coverage for outpatient therapy services¹ that includes physical therapy, occupational therapy, and speech language pathology services. Physical therapists evaluate and treat disorders of the musculoskeletal system. The goal of physical therapy is to restore maximal functional independence to each individual patient by providing services that aim to restore function, improve mobility and relieve pain. Modalities such as exercise, heat, cold, electricity and massage are used. These services are provided in a number of different settings; however, the majority of Medicare payments for outpatient therapy services are made to physical therapists practicing in an office setting.

¹ Sections 1832(a)(2)(C) and 1861(p) of the Act.

For Medicare Part B to cover outpatient physical therapy services, it must be medically reasonable and necessary, the services must be provided in accordance with a plan of care (plan) established by a physician or qualified therapist and periodically reviewed by a physician, and the need for such services must be certified by a physician.² Further, Medicare Part B pays for outpatient physical therapy services billed using standardized codes³ and performed by or under the personal supervision of a therapist in private practice.⁴ Finally, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.⁵

These requirements are further clarified in chapter 15 of CMS's *Medicare Benefits Policy Manual* (Pub. 100-02) and in chapter 5 of its *Medicare Claims Processing Manual* (Pub. 100-04).

Illinois Physical Therapist

The selected physical therapist operates two physical therapy offices and provides additional physical therapy services at a chiropractic office located in the State of Illinois.

During our audit period (January 1 through December 31, 2011), Wisconsin Physicians Services Insurance Corporation was the Medicare Administrative Contractor (MAC) for providers in Jurisdiction 6, which included Illinois. National Government Services assumed full responsibility as the Medicare contractor for Jurisdiction 6 effective September 7, 2011.

HOW WE CONDUCTED THIS REVIEW

Our review covered a therapist's claims for Medicare outpatient physical therapy services provided from January 1 through December 31, 2011. Our sampling frame consisted of 4,298 outpatient physical therapy service claims,⁶ totaling \$645,966, of which we reviewed a simple random sample of 100 claims.

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.

² Sections 1862(a)(1)(A) and 1835(a)(2) of the Act.

³ Standardized codes used by providers are called Healthcare Common Procedure Coding System (HCPCS) codes to report units of service.

⁴ 42 CFR §§ 410.59 and 410.60.

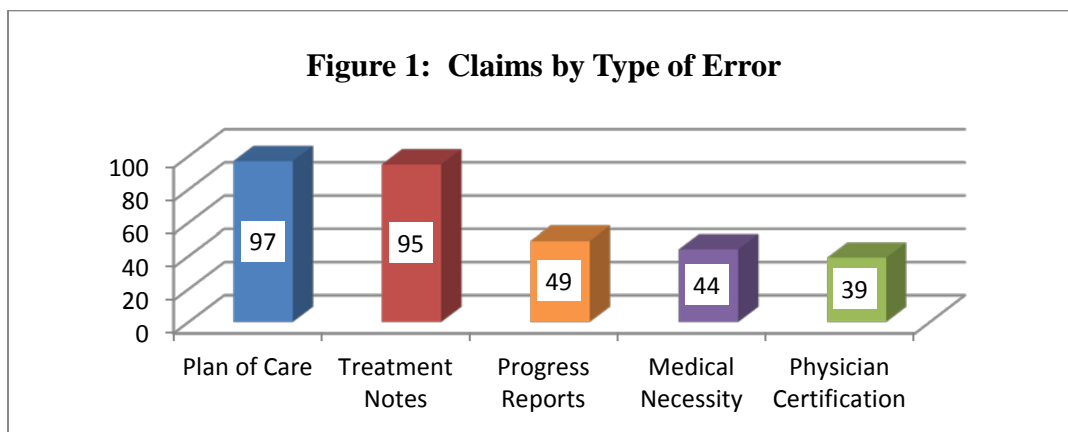
⁵ Section 1833(e) of the Act.

⁶ A claim consisted of all payments made for a beneficiary on the same date of service.

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 a summary of the sample errors.

FINDINGS

The therapist claimed Medicare reimbursement for outpatient physical therapy claims that did not meet Medicare reimbursement requirements. Specifically, of the 100 claims in our random sample, the therapist improperly claimed Medicare reimbursement on 99⁷ claims, all of which contained more than one deficiency as shown in Figure 1. The therapist properly claimed Medicare reimbursement on the remaining claim.



As illustrated above:

- 97 claims did not meet Medicare’s plan of care requirements,
- 95 claims did not meet Medicare’s treatment note requirements,
- 49 claims had progress reports that were untimely or not contained in the medical record,
- 44 claims had therapy services that were not medically necessary, and
- 39 claims did not meet Medicare’s physician certification requirements.

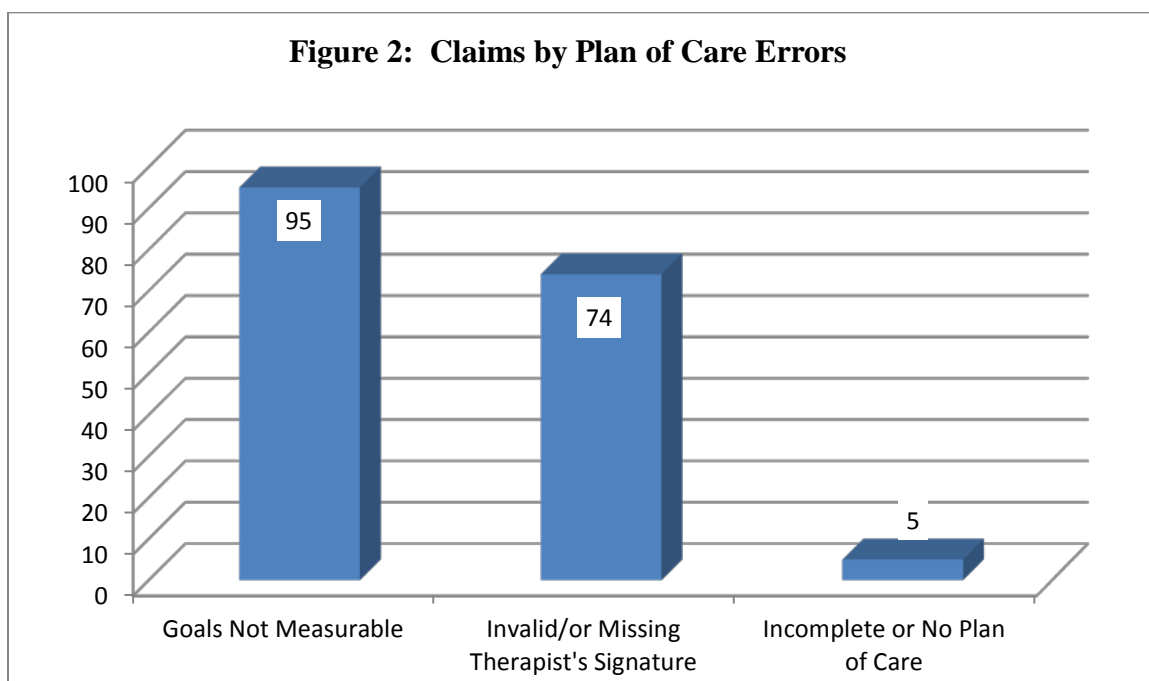
These deficiencies occurred because the therapist did not have adequate policies and procedures in place to ensure that the therapist billed for services that met certain Medicare requirements. On the basis of our sample results, we estimated that the therapist improperly received \$634,837 in Medicare reimbursement for outpatient physical therapy services that did not comply with Medicare requirements.

⁷ The total errors exceed 99 because claims contained more than one error.

PLAN OF CARE DID NOT MEET MEDICARE REQUIREMENTS

Outpatient physical therapy services must be provided in accordance with a written plan established before treatment begins (42 CFR § 410.60). The plan must contain the type, amount, frequency, and duration of the occupational or physical therapy services to be furnished and must indicate the diagnosis and anticipated goals (42 CFR § 410.61). Goals should be measurable and pertain to identified functional impairments. In addition, the signature and professional identity of the person who established the plan and the date it was established must be recorded (*Medicare Benefit Policy Manual*, chapter 15, §§ 220.1.2A and B).

For 97⁸ claims, the therapist received Medicare reimbursement for services that were not provided in accordance with a plan of care that met Medicare requirements as shown in Figure 2.



Specifically:

- For 95 claims, the goals were not measurable or pertained to identified functional impairments. For example, the therapist received payment for physical therapy services provided on June 9, 2011, to a 72-year-old Medicare beneficiary. The therapist provided a plan of care that was generally vague with short term goals to decrease the level of chronic pain and long term goals to improve the patient's range of motion, strength, tone and gait/balance. However, the patient received nearly 6 months of repetitive therapy with no objective evidence of measurable progress or need of services of a skilled therapist.

⁸ The total errors exceed 97 because the plan of care on these claims contained more than one error.

- For 74 claims, the therapist’s signature did not meet Medicare requirements. Specifically, 73 of these claims relate to electronic medical records that did not contain a contemporaneous signature at the time the plan of care was prepared. At the time of our audit, the therapist used an unsecured rubber stamp to manually stamp these claims. Stamp signatures are not an allowable form of signature. For the remaining manual claim, the therapist did not sign the plan.
- For five claims, the plan of care was missing or incomplete.

TREATMENT NOTES DID NOT MEET MEDICARE REQUIREMENTS

Medicare payments should not be made without the information necessary to determine the amount due the provider (section 1833(e) of the Act). In addition, a provider must furnish to its MAC sufficient information to determine whether payment is due and the amount of payment (42 CFR § 424.5(a)(6)).

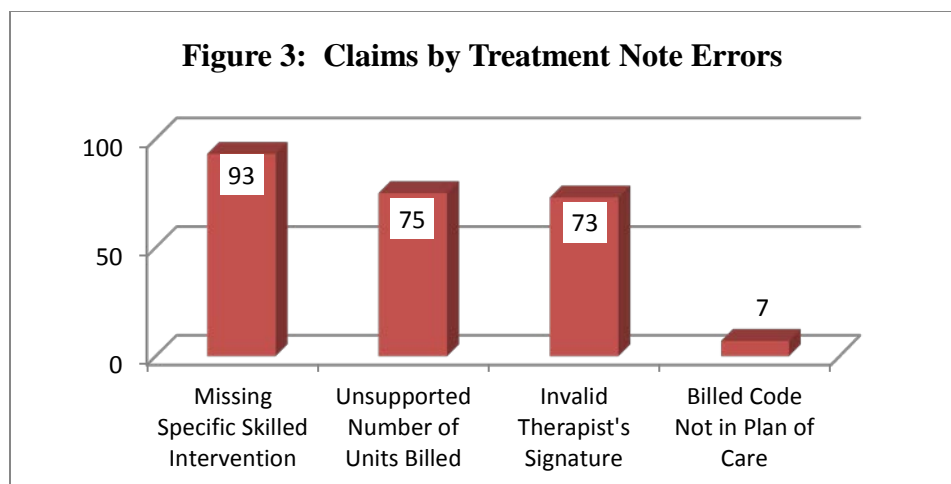
Outpatient therapy services are payable when the medical record and information on the provider’s claim form consistently and accurately report covered services (*Medicare Benefit Policy Manual*, chapter 15, § 220.3A). In addition, providers must report the number of units for outpatient rehabilitation services based on the procedures or services provided. For timed procedures, units are reported in 15-minute intervals. For untimed procedures, units are reported based on the number of times the procedure is performed (*Medicare Claims Processing Manual*, chapter 5, § 20.2).

Therapists must maintain a treatment note for each treatment day and each therapy service. The treatment note must document the: (1) date of treatment, (2) identification of each specific service provided and billed, (3) total timed code treatment minutes and total treatment time in minutes, and (4) signature and professional identification of the therapist who furnished or supervised the service (*Medicare Benefit Policy Manual*, chapter 15, § 220.3E). A Local Coverage Determination (LCD) related to signatures states that stamp signatures are not an acceptable form of signature.⁹

For 95¹⁰ claims, the therapist received Medicare reimbursement for services for which the treatment notes did not meet Medicare requirements as shown in Figure 3.

⁹ LCD Number L28531, Outpatient Rehabilitation Therapy Services billed to Medicare Part B, it states, “Effective April 28, 2008, stamp signatures were no longer acceptable.”

¹⁰ The total errors exceed 95 because treatment notes on claims contained more than one error.



Specifically:

- For 93 claims, the treatment notes did not indicate the specific interventions/modalities provided to verify that the correct HCPCS codes were billed. For example, the therapist received payment for physical therapy provided under HCPCS code 97110 on February 10, 2011, to a 71-year old Medicare beneficiary. The therapist provided treatment notes stating that the “therapeutic exercise applied to: the lumbar back, the trunk, and the lower extremities bilaterally (30 minutes).” However, the treatment notes did not indicate what specific therapeutic exercises were performed to warrant the billing of HCPCS code 97110.
- For 75 claims, the treatment notes did not support the number of units billed. For 71 of these claims, the treatment notes did not document total minutes as required by Medicare for timed HCPCS codes. For the remaining 4 claims, more units were billed than were supported by the treatment notes.
- For 73 claims, the treatment notes did not have a valid therapist signature as required by Medicare policy. Specifically, these claims related to electronically kept medical records that did not contain a contemporaneous signature at the time the treatment notes were prepared. For these claims, the therapist used an unsecured rubber stamp to manually stamp the claims at the time these claims were provided to us for audit. Stamp signatures are not an allowable form of signature.
- For seven claims, the therapist billed a code for services that were not prescribed by the plan of care.

UNTIMELY OR MISSING PROGRESS REPORTS

The minimum progress report period shall be at least once every 10 treatment days or at least once each 30 calendar days, whichever is less. (*Medicare Benefit Policy Manual*, (Pub. 100-02) § 220.3D).

For 42 claims, progress reports were not made at least once every 10 treatment days or at least once during each 30 calendar days, whichever was less. For an additional seven claims, there were no progress reports as required by Medicare regulations.

SERVICES NOT MEDICALLY NECESSARY

The Balanced Budget Act of 1997 placed an annual cap on Medicare rehabilitation services. Financial limits called “therapy caps” apply to outpatient Part B therapy services.¹¹ Exceptions to therapy caps are authorized if services are medically necessary and identified by a “KX modifier” on the claim. The modifier is added to a claim to indicate that the provider attests that services are medically necessary and that justification is documented in the medical record (*Medicare Claims Processing Manual*, chapter 5, §§ 10.2 and 10.3).

No payment may be made under Medicare Part A or Part B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (section 1862(a)(1)(A) of the Act).

For 44¹² claims, the therapist received Medicare reimbursement for which the beneficiaries’ medical record did not support the medical necessity of services. The results of the medical review¹³ indicated that these services did not meet one or more Medicare requirements:

- Goals in plans of care were not measurable (35 services).
- Invalid or missing certification of the plans of care (35 services).
- Overall medical record documentation failed to support medical necessity (25 services).
- Physical therapy was repetitive with no evidence that skilled therapy services were needed (24 services).

For example, the therapist received payment for physical therapy provided on June 30, 2011, to a 74-year old Medicare beneficiary. The medical review contractor determined that the therapy service did not meet Medicare coverage requirements as the medical records failed to support that the functional ability was impaired to the degree that would require therapy beyond the implementation of a home exercise program. This patient had received services beyond the Medicare cap by receiving approximately 6 months of therapy and there was no objective evidence of progress in the medical record.

¹¹ Therapy caps were established for (1) combined physical and speech therapy services and (2) occupational therapy services and were based on therapy services that the beneficiary received. For calendar year 2011, the therapy caps for each were \$1,870.

¹² Of the 44 claims, 43 were for services over the therapy cap. As such, the therapy provider billed these 43 claims with the KX modifier.

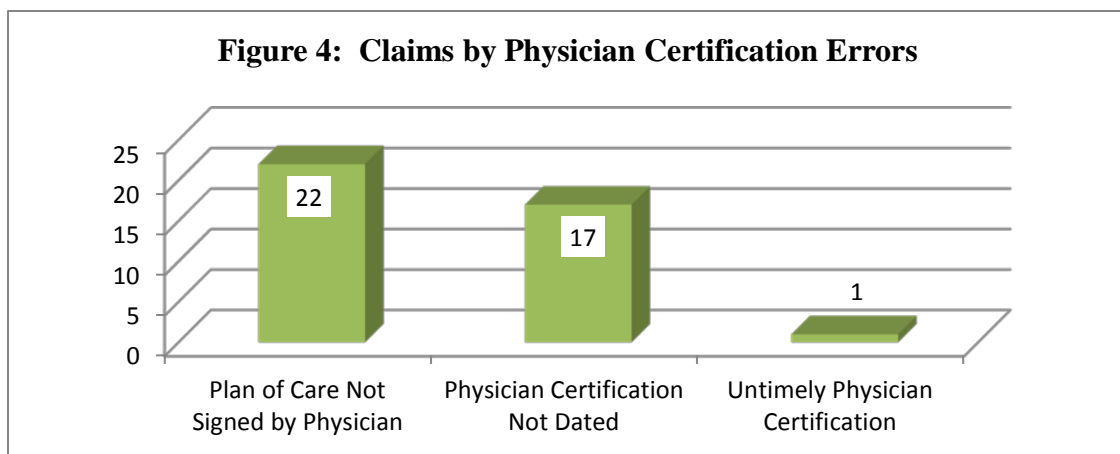
¹³ Of the 44 claims, 43 were reviewed by an independent medical review contractor and one claim was reviewed by the Medicare Administrative Contractor.

PHYSICIAN CERTIFICATION DID NOT MEET MEDICARE REQUIREMENTS

Payment for outpatient therapy services may be made if a physician certifies: (i) that such services were required because the individual needed outpatient therapy, (ii) a plan for furnishing such services has been established by a physician or by a qualified therapist and periodically reviewed by a physician, and (iii) such services were furnished while the individual was under the care of a physician (section 1835(a)(2)(C) of the Act).

Initial certifications must be obtained as soon as possible after the plan is established and must be signed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant who has knowledge of the case (42 CFR § 424.24(c)(2) and (3)). Initial certification requirements are satisfied by a physician or non-physician practitioner's certification of the initial plan. For an initial plan to be certified in a timely manner, the physician or non-physician practitioner must certify the initial plan as soon as it is obtained or within 30 days of the initial treatment. For recertification, the plan must be dated during the duration of the initial plan of care or within 90 calendar days of the initial treatment under that plan, whichever is less (*Medicare Benefit Policy Manual*, chapter 15, § 220.1.3.D). Physician certification is documented by a dated signature or verbal order (*Medicare Benefit Policy Manual*, chapter 15, § 220.1.3.B).

For 39¹⁴ claims, the therapist received Medicare reimbursement for services that did not meet Medicare physician certification requirements as shown in Figure 4.



Specifically:

- For 22 claims, the physician certification on the initial plan of care or the recertification for subsequent therapy services was missing.
- For 17 claims, the physician certification was not dated to determine whether the physician certification was timely.
- For one claim, the physician certification of the beneficiary's initial plan was untimely.

¹⁴ The total errors exceed 39 because one claim contained more than one error.

CONCLUSION

On the basis of our sample results, we estimated that the therapist improperly received at least \$634,837 in Medicare reimbursement for outpatient physical therapy services that did not comply with certain Medicare requirements.

RECOMMENDATIONS

We recommend that the therapist:

- refund \$634,837 to the Federal Government and
- establish adequate policies and procedures to ensure that outpatient physical therapy services billed to Medicare are medically necessary, correctly coded, and adequately documented.

THERAPIST'S COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the therapist, through his attorneys, disagreed with our findings and recommendations. The therapist's comments are included in their entirety as Appendix E.

After reviewing the information provided in the therapist's written comments, we maintain that our findings and recommendations are valid. Below is a summary of the therapist's comments as well as our response to those comments.

Plan of Care

Goals Not Measurable

The therapist disagreed that denial on the basis of failure to include "measurable goals" was inappropriate. The therapist believes that the cited criterion stating "should be measurable" do not indicate a mandated requirement and that this is consistent with the provisions of the *Jimmo* settlement.

We maintain that 95 claims did not meet the requirements for plans of care. To provide a valid and payable service, outpatient physical therapy services must meet the definition of "outpatient physical therapy services" section 1861(p) of the Act, which includes the requirement that services be provided "with respect to whom a plan prescribing the type, amount, and duration of physical services that are to be furnished...." Requirements specific to plans of care for outpatient therapy services were established in 42 CFR § 410.61. Under 42 CFR § 410.61(c), plans of care must indicate "the diagnosis and anticipated goals." The *Medicare Benefit Policy Manual*, chapter 15, §§ 220.1.2.A and B, provides clarifying guidance related to the required contents of the plan of care. Under § 220.1.2.B, plans of care must include long-term treatment goals, which "should be measurable and pertain to identified functional impairments" consistent

with the requirements of 42 CFR § 410.61. However, § 220.1.2.B also recognizes “that measurable goals may not be achievable...” documentation should state the clinical reasons progress cannot be shown. In our review of the claims and the associated plans of care, documentation did not meet the minimum requirements for including information on long-term treatment goals. Additionally, there was no documentation that explained why long-term measurable goals were not achievable.

Invalid/or Missing Therapist’s Signature

The therapist believes that a signature is neither applicable nor expressly required in a plan of care. Additionally, the therapist believes that for electronic claims, a contemporaneous signature is not possible nor a condition of payment.

We maintain that the 74 claims did not meet requirements for plans of care under *Medicare Benefit Policy Manual*, chapter 15, § 220.1.2.A, which requires the signature of and professional identity of the individual who established the plan. Exception 3 in the *Program Integrity Manual* § 3.3.2.4 states that “CMS’ instructions regarding conditions of payment related to signatures...take precedence.” Additionally, *Program Integrity Manual* § 3.3.2.4, states that stamp signatures are not acceptable. While onsite, we were provided records, including plans of care, that were printed and then stamp signed to indicate the physical therapist who established the plan of care. We were not provided any documentation that these claims included an electronic signature of the physical therapist who established the plan of care. Plans of care that only had the stamped signature made at the time documents were provided in response to our audit do not meet the relevant requirements to establish a valid plan of care.

Incomplete or No Plan of Care

The therapist stated that we did not identify the specific issues supporting the missing or incomplete plans of care. It also stated that the required information can be inferred from the record as a whole.

We maintain that in order to determine the allowability of a claim, we needed a complete plan of care. Outpatient physical therapy services must be provided in accordance with a written plan established before treatment begins. The plan must contain the type, amount, frequency, and duration of the occupational or physical therapy services to be furnished and must indicate the diagnosis and anticipated goals (42 CFR § 410.61). For one of the claims, there was no plan of care in the medical record. For four of the claims, the plans of care were missing various required elements such as short and/or long-term goals, frequency of therapy duration, or therapist’s signature.

Treatment Notes

Missing Specific Skilled Intervention

The therapist believes that denial on the basis of not indicating the specific interventions/modalities in the treatment notes is not an identified condition of payment.

We maintain that 93 claims did not meet Medicare treatment note requirements because they did not indicate the specific interventions/modalities provided. Specifically, Medicare payments should not be made without the information necessary to determine the amount due the provider (section 1833(e) of the Act). In this respect, therapists must maintain a treatment note for each therapy service that contains the: (1) date of treatment, (2) identification of each specific service provided and billed, (3) total timed code treatment minutes and total treatment time in minutes, and (4) signature and professional identification of the therapist who furnished or supervised the service (*Medicare Benefit Policy Manual*, chapter 15, § 220.3.E).

Unsupported Number of Units Billed

The therapist believes that for 71 claims the amount of time spent in performance of each time-based service was indicated in the medical record and that the total time spent can be easily inferred. For the remaining four claims, the therapist acknowledged that the documentation was deficient, however, believes that it provided us testimonial evidence. Finally, the therapist believes that a documentation deficiency is not a condition of payment.

We disagree that the 71 claims referred to by the therapist contained information relative to the time spent in performance of each time-based service. The 71 claims did not include total treatment time in minutes as required by *Medicare Benefit Policy Manual*, chapter 15, § 220.3.E. Without this information, the treatment notes did not include required information to “record the time of the services in order to justify the use of billing codes on the claim.” For the remaining 4 claims we reviewed the testimonial evidence provided, but maintain that there is still insufficient evidence that units billed were supported by the treatment notes or additional testimonial evidence.

Invalid Therapist’s Signature

The therapist believes that a signature on the treatment note is not a condition of payment and that its use of his own signature stamp to attest to his created notations meets the spirit of the attestation rules. As such, this defect is correctable with an attestation.

We maintain that the 73 claims did not meet requirements for treatment notes under *Medicare Benefit Policy Manual*, chapter 15, § 220.3.E, which requires “[s]ignature and professional identification of the qualified professional who furnished or supervised the service.” Exception 3 in the *Program Integrity Manual* § 3.3.2.4 states that “CMS’ instructions regarding conditions of payment related to signatures...take precedence.” Additionally, *Program Integrity Manual* § 3.3.2.4, states that stamp signatures are not acceptable. While onsite, we were provided records,

including treatment notes, that were printed and then stamp signed to indicate the professional who furnished or supervised the service. We were not provided any documentation that these claims included an electronic signature in the treatment note to indicate the professional who furnished or supervised the service. Treatment notes that only had the stamped signature made at the time documents were provided in response to our audit do not meet the documentation requirements for treatment notes.

Billed Code Not in Plan of Care

The therapist believes that there is no evidence that we considered whether a change in plan was appropriate and permitted. The therapist believes that changes to the plan of care were evident in the daily notations and that minor changes he made to the plan of care did not constitute a major change to the plan of care.

We disagree with the therapist's assertions and maintain that seven claims were billed for services not included in the plan of care. Outpatient physical therapy services must be provided in accordance with a written plan established before treatment begins. The plan must contain the type, amount, frequency, and duration of the occupational or physical therapy services to be furnished and must indicate the diagnosis and anticipated goals (42 CFR § 410.61). Further, as a condition of coverage under the *Medicare Benefit Policy Manual*, chapter 15, § 220.1.2A, "the services must relate directly and specifically to a written treatment plan as described in this chapter." Further, the services provided amounted to significant changes in the plan of care and did not include the appropriate certification of those changes in accordance with the *Medicare Benefit Policy Manual*, chapter 15, § 220.1.2.C.

Untimely or Missing Progress Reports

The therapist believes progress reports, while required to justify the necessity of the treatment, are not required as a condition of payment. The therapist believes that our allegation of error is based on perceived content deficiencies as opposed to standards of necessity.

We maintain that 42 claims and an additional 7 claims did not include required documentation for timely progress reports or were missing progress reports. According to *Medicare Benefit Policy Manual*, chapter 15, § 220.3.A, the documentation guidelines in this section identify the minimal expectations of documentation by providers or suppliers or beneficiaries submitting claims for payment of therapy services to the Medicare program. Additionally, progress notes provide justification for the medical necessity of treatment. (*Medicare Benefit Policy Manual*, chapter 15, § 220.3.D). For the 42 claims that included untimely progress reports, the reports were not made within the 7-day grace period and did not provide documentation that the "clinician did not participate actively in treatment during the progress report period."

Services Not Medically Necessary

The therapist believes that our conclusion regarding goals was made under the presumption that measurable goals are required and states that this is inconsistent with the *Jimmo* case.

Additionally, the therapist believes that a certification of the plan of care is a condition of payment unrelated to the necessity of care and that our review ignored the provision of delayed certification. Finally, the therapist stated that we did not provide specific facts for the conclusion that documentation failed to support medical necessity and that using “no objective progress” as a basis for determination is contrary to CMS disavowing the “improvement standard” as a predicate for the coverage in the *Jimmo* settlement.

We submitted these claims to an independent medical review contractor to determine whether the services met medical necessity. Specifically, the determination that the therapist received Medicare reimbursement for services for which the medical record did not support the medical necessity of the services above the therapy cap was made by two clinicians - one of them being a physical therapist and the other a board certified physician in the field of physical medicine and rehabilitation. The medical review staff have extensive knowledge of the Medicare requirements related to medical necessity and, on the basis of their review of the medical records, concluded that therapist’s documentation did not justify services above the therapy cap.

Physician Certification

The therapist acknowledged that certifications must be signed and dated, but stated that we ignored the CMS provision that allows for delayed certifications, which it has obtained for appropriate certification.

Of the 39 claims with deficiencies, we identified 38 claims that either did not have a physician signature or lacked a date on the physician certification to determine whether the certification was timely. For the remaining claim, we reviewed a delayed certification during our field work that still did not meet Medicare delayed certification requirements. 42 CFR § 424.11(d)(3) allows for delayed certification and recertification statements when there is a legitimate reason. These statements must include an explanation for the delay. The therapist’s response and the medical records did not specify the reasons for the delay as required.

Statistical Sampling

The therapist believes it has identified numerous problems in our statistical sampling methodology. The therapist believes excluding unpaid claims and claims less than \$25 from the sample would bias the projected financial error to yield a higher overpayment amount. The therapist also stated that we did not divulge the basis for determining the sample size, which is necessary to determine the appropriate sample size. Finally, the therapist believes that the non-statistical nature of the projection is evident given that the point estimate from the projection calculations yielded an amount in excess of the total value of all claims in the sampling frame - suggesting that the sample was not representative of the universe.

Federal courts have established the use of statistical sampling and estimation as a viable audit technique.¹⁵ Questioning whether the sample could have been more precise or optimal does not indicate that our methodology was invalid.¹⁶ We properly executed our statistical sampling methodology in that we have defined our sampling frame and sample unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and applied the correct formulas for the estimation.

With respect to sample size, the Medicare Program Integrity Manual indicates that it is neither possible nor desirable to specify a minimum sample size that applies to all situations. A challenge to the validity of the sample that is sometimes made is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design. As sample sizes decrease so does the estimated overpayment amount at the lower limit of the confidence interval, thus giving the benefit of a smaller sample to the Medicare provider.¹⁷

Furthermore, our use of statistical sampling by no means removes the therapist's right to appeal the individual determinations on which the estimation is based through the normal appeals process.¹⁸

Therefore, we continue to recommend that the therapist refund to the Medicare program \$634,837 in estimated overpayments for CY 2011 and that it strengthen controls to ensure full compliance with Medicare requirements.

¹⁵ Chaves County Home Health Service, Inc. v. Sullivan, 931 F.2d 914 (D.C. Cir. 1991).

¹⁶ Miniet v Sebelius, No. 10-24127-CIV (S.D. Fla. 2012).

¹⁷ Schuldt Chiropractic Wellness Center v Sebelius, No. 8:13CV4 (D. Neb. 2014).

¹⁸ Pruchniewski v. Leavitt, No. 08:04-CV-2200-T-23TBM (M.D. Fla 2006).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 4,298 Medicare outpatient physical therapy services, totaling \$645,966, provided by the therapist from January 1 through December 31, 2011. A claim consisted of all payments made for a beneficiary on the same date of service. These claims were extracted from CMS's National Claims History file.

We limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of the therapist's policies and procedures for documenting and billing Medicare for outpatient therapy services. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

We conducted our fieldwork at the therapist's offices in Illinois, from January through September 2013.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations and guidance;
- interviewed Medicare officials to obtain an understanding of the Medicare requirements related to outpatient therapy services;
- interviewed the therapist to gain an understanding of its policies and procedures related to providing and billing Medicare for outpatient therapy services;
- extracted from CMS's National Claims History file a sampling frame of 4,298 outpatient therapy service claims, totaling \$645,966, from January 1 through December 31, 2011;
- selected a simple random sample of 100 outpatient therapy service claims from the sampling frame (Appendixes B and C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;
- obtained and reviewed case record documentation from the therapist for each sample claim to determine whether the services were provided in accordance with Medicare requirements;

- used an independent medical review contractor to determine whether 43 sampled claims met medical necessity requirements;
- used the MAC to determine whether one sampled claim met medical necessity requirements;
- used the results of the sample review to calculate the estimated unallowable Medicare reimbursement paid to the therapist (Appendix C); and
- discussed the results of our review with the therapist.

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

POPULATION

The population consisted of all Medicare Part B outpatient therapy service claims paid to the therapist from January 1 through December 31, 2011.

SAMPLING FRAME

The sampling frame was an Access database containing 4,298 outpatient therapy service claims, totaling \$645,966, provided by the therapist from January 1 through December 31, 2011. The claims data were extracted from the CMS National Claims History file.

SAMPLE UNIT

The sample unit was an outpatient therapy service claim from January 1 through December 31, 2011, for which the therapist claimed Medicare reimbursement. A claim consisted of all payments made for a beneficiary on the same dates of service. The claims were limited to payment amounts greater than or equal to \$25.

SAMPLE DESIGN

We used a simple random sample to review Medicare payments made to the therapist for outpatient therapy services.

SAMPLE SIZE

We selected a sample of 100 outpatient therapy service claims.

SOURCE OF THE RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the sampling frame. After generating 100 random numbers, we selected the corresponding frame items. We then created a list of the 100 sampled items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to appraise the sample results. We estimated the total amount of inappropriate Medicare payments for unallowable outpatient therapy services made to the therapist at the lower limit of the 90-percent confidence level.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Claims in Frame	Value of Frame	Sample Size	Value of Sample	Number of Unallowable	Value of Unallowable Claims
4,298	\$645,966	100	\$16,492	99	\$16,060

ESTIMATES

Estimated Value of Unallowable Claims

(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$690,255
Lower Limit	634,837
Upper Limit	745,673

APPENDIX D: SUMMARY OF SAMPLE ERRORS
Legend

	Description of Error
A	Plan of care did not meet Medicare requirements
B	Treatment notes did not meet Medicare requirements
C	Untimely or missing progress reports
D	Therapy services were not medically necessary
E	Physician certifications did not meet Medicare requirements

Sample Number	A	B	C	D	E	Total Errors
1	X	X				2
2	X				X	2
3	X	X	X			2
4	X	X	X	X		3
5	X	X				2
6	X	X			X	3
7	X	X	X	X		4
8	X	X				2
9	X	X	X	X	X	5
10	X	X	X	X	X	5
11	X	X	X	X		4
12	X	X	X	X	X	5
13	X	X			X	3
14	X	X	X		X	4
15	X	X	X			3
16	X	X	X	X	X	5
17	X	X			X	3
18	X				X	2
19						0
20	X	X			X	3
21	X	X				2
22	X	X		X		3
23	X	X			X	3
24	X	X	X	X	X	5
25	X	X		X		3
26	X	X		X		3
27	X	X	X	X	X	5
28	X	X			X	3
29	X	X		X		3

Sample No.	A	B	C	D	E	Total Errors
30	X	X				2
31	X	X			X	3
32	X	X	X	X		4
33	X	X			X	3
34	X	X	X	X	X	5
35	X	X			X	3
36	X	X			X	3
37	X	X	X			3
38	X	X			X	3
39	X	X	X	X	X	5
40	X		X	X	X	4
41	X	X	X	X		4
42	X	X				2
43	X	X	X	X	X	5
44	X	X	X		X	4
45	X	X	X	X	X	5
46	X	X				2
47	X	X	X	X		4
48	X	X	X		X	4
49	X	X	X			3
50	X	X		X		3
51	X	X		X		3
52	X	X				2
53		X		X	X	3
54	X	X				2
55	X	X	X	X		4
56	X	X	X			3
57	X	X				2
58	X	X				2
59	X	X				2
60	X	X	X		X	4
61	X	X				2
62		X			X	2
63	X	X	X	X		4
64	X	X	X	X		4
65	X	X				2
66	X	X		X	X	4
67	X	X	X		X	4
68	X	X		X		3

Sample No.	A	B	C	D	E	Total Errors
69	X	X	X			3
70	X	X			X	3
71	X	X	X		X	4
72	X	X			X	3
73	X	X			X	3
74	X	X	X	X		4
75	X	X				2
76	X	X	X	X		4
77	X	X				2
78	X	X	X	X		4
79	X	X				2
80	X	X	X	X		4
81	X	X	X	X		4
82	X	X		X		3
83	X	X		X		3
84	X	X				2
85	X	X	X			3
86	X	X	X		X	4
87	X	X				2
88	X	X	X	X		4
89	X	X				2
90	X	X	X	X		4
91	X	X	X	X		4
92	X		X	X	X	4
93	X	X	X	X		4
94	X	X			X	3
95	X	X	X			3
96	X	X	X			3
97	X	X	X	X		4
98	X	X	X	X		4
99	X	X	X	X		4
100	X	X				2
Totals	97	95	49	44	39	

APPENDIX E: THERAPIST'S COMMENTS

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April 25, 2014

PARALEGAL
PHILIP GZESH

TO: Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan Avenue, Suite 1360
Chicago, Illinois 60601

FROM: Goldberg Law Group, LLC
Representative for Physical Therapist

SUBJECT: Office of Inspector General (OIG) Draft Report: "An Illinois Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services" (A-05-13-00010)

Dear Ms. Fulcher,

Thank you for the opportunity to review and comment on the subject OIG draft report. The physical therapist that was subject of the audit has asked our office to respond to your letter as his representative.

As a preliminary matter, the executive summary states that this therapist was selected based on the total volume of Medicare billings. The therapist was identified as one of the "highest Medicare therapy billers in the State of Illinois." The OIG has not disclosed whether the volume of this therapist's total billings was compared to other individual therapists or group practices.

Based on our review of the sample claims and Medicare requirements, we have noted a large number of discrepancies in the OIG's findings and recommendations as discussed below.

Response to OIG's Findings of Alleged Error

1. 97 of the 100 claims sampled were alleged to be in error because the documentation did not support Medicare's plan of care requirements.

Specific Allegations:

- a. For 95 claims, the OIG alleges that the plan of care did not include “measurable goals that pertained to identified functional impairments.”

Response: The Medicare Benefit Policy Manual (“MBPM”) provision cited that was in effect at the time services were rendered establishes no condition of payment requiring that a plan of care contain “measurable goals that pertained to identified functional impairments.” IOM Pub 100-2, Chapter 15 §§220.1.2A and B. The provision (cited from Revision 126 of the MBPM, effective May 21, 2010 and which was unchanged through the review period) requires at a minimum that the plan contain “diagnoses; long term treatment goals; and the type, amount, duration and frequency of therapy services.” Relative to the requirement for long term goals, the MBPM provides further explanation stating that goals “*should* be measurable and pertain to identified functional impairments.” (emphasis added). It is noted that the use of the word “should” does not indicate a mandated requirement. Instead, this provision suggests that therapists establish measurable goals where possible or relevant. Such a conclusion is justified when we consider that most objective problems for which physical therapy is appropriate are not capable of quantifiable measure and therefore it is impossible to establish measurable goals. Additionally, it must be noted that even if the guidance could be construed as requiring measurable goals, this is different than the establishment of a measure ascertaining when the goal is met. A goal such as improving gait is “measurable” based on the fact that subsequent assessment of gait by the therapist can be objectively evaluated. The OIG, however, seems to require a quantifiable standard establishing when the goal will be met. Such a requirement is not supported by the MBPM provision cited and would be unattainable for most conditions since there is no clinically accepted basis for establishing the degree of deficit for most conditions, including gait.

Notwithstanding the foregoing, denial of payment on this basis is not appropriate. The provisions of Section 220.1 of MBPM which establish the express “Conditions of Coverage and Payment for Outpatient Physical Therapy” do not require “measurable long term goals.” It is noted that these provisions, which are consistent with the regulatory provisions at 42 CFR §424.24, establish that there must be a plan of care established by a physician/NPP or by the therapist providing service, but do not preclude payment where the long term goals are not measurable. Such a conclusion is consistent with the provisions of the *Jimmo* settlement wherein CMS acknowledged that there is no requirement for improvement under the regulatory provisions and CMS guidance pertaining to physical therapy. To the extent that the ostensible purpose of measurable goals pertaining to functional impairments is to provide a basis for measuring the amount of improvement achieved by physical therapy services as a means of establishing the necessity of the care, and because *Jimmo* established that improvement is not required as a condition of payment, such a requirement serves no apparent purpose consistent with CMS’ failure to identify

“measureable goals” as a condition of payment. As a result, denial on this basis is inappropriate.

- b. For 74 claims, the OIG alleges that the plan was invalid because it did not include a contemporaneous signature at the time the plan of care was prepared.

Response: OIG recognized that the documentation associated with 73 of the 74 claims was recorded electronically. As such, a contemporaneous signature is not possible. A contemporaneous signature is not a condition of payment as acknowledge in Section 220.1 of the MBPM. Additionally, CMS addresses the issue of signatures in its Program Integrity Manual, IOM Pub 100-8, Chapter 3, Section 3.3.2.4. Under these provisions, denial on this basis was inappropriate.

Under Exception 3 of Section 220.1, where the “relevant regulation, NCD, LCD and CMS manuals are silent on whether the signature needs to be legible or present and the signature is illegible/missing, the reviewer shall follow the guidelines listed below to discern the identity and credentials (e.g., MD, RN, etc.) of the signator. In cases where the relevant regulation, NCD, LCD and CMS manuals have specific signature requirements, those signature requirements take precedence.”

In this case, the relevant regulation is 42 C.F.R. §424.24. This provision establishes a signature requirement for certification of the plan of care, but not the plan of care itself. Similarly, the MBPM provisions establishing the conditions of payment are silent as to signatures. The guidance relative to the contents of a plan are found in the MBPM at Section 220.1.2.B. No provision establishes a signature requirement for a plan of care. The relevant version of LCD L28531 in effect during the review period establishes that a plan of care must be certified by a physician/NPP and that the physician/NPP is responsible for reviewing, signing and dating the plan. There is no express requirement that the plan be signed and dated by the therapist. LCD L28531 does include, as part of the documentation requirements section, a provision stating, “Medicare requires a legible identifier of the person(s) that provided the service.” The provision also states that effective April 28, 2008, stamped signatures are not acceptable. This provision, however, appears to apply to treatment notes and not to the plan of care. As there is no express signature requirement for the plan of care, especially one that establishes a condition of payment, the Program Integrity Manual (“PIM”) requires acceptance of a signature attestation from the author of the medical record.

As there are no specific format requirements for an attestation, the fact that the therapist that recorded the electronic notation is the same person that applied the signature stamp containing his name to the electronic notations above his typewritten name (in response to the OIG request for medical records), the OIG should consider that the attestation requirements are satisfied. To the extent that further attestation is necessary, this is easily provided and the allegations associated with these 74 claims would not justify denial.

c. For 5 claims, the OIG alleges that the plan of care was missing or incomplete.

Response: The OIG does not identify the specific issues supporting the allegations. Additionally, it is noted that the spreadsheet data provided indicates only three claims where this error was attributed. In each case, the plan of care does not explicitly address the type, frequency or duration of care, or the anticipated goals of care; however, this information is evident when the documentation is reviewed as a whole. We believe that because the required information can be inferred from the record as a whole, the requirement is satisfied.

2. 95 of the 100 claims sampled were alleged to be in error because the documentation did not meet Medicare's treatment note requirements.

As a preliminary matter, OIG cites section 1833(e) of the Social Security Act ("the Act"), which states that "[n]o 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." (emphasis added). For CMS to "determine the amounts due", the only information required is a CPT or HCPCS code. Additionally, the requirement of "information" under this section of the Act cited should not be construed as meaning "documentation." According to the HHS OIG Office of Audit Services document entitled "The Audit Process" (2nd ed., January 2005), information includes physical, analytical, documentary and testimonial evidence.

The OIG also cites the companion regulatory provision, 42 CFR §424.5(a)(6), which requires "[t]he provider, supplier, or beneficiary, as appropriate, [to] furnish to the intermediary or carrier sufficient *information to determine whether payment is due and the amount of payment.*" While the focus remains on "information" as opposed to documentation, it is noted that the regulatory provision also requires the provider to supply information to "determine whether payment is due." Ostensibly, the regulation is implying a requirement for information to determine whether services were medically necessary, or otherwise met the stated conditions of payment as expressed at 42 CFR §424.24 and further detailed in the MBPM at Section 220.1. Because compliance with CMS guidance pertaining to the content of a treatment note is not an express condition of payment, the regulatory demand for information necessary to determine the appropriateness of payment cannot be construed as requiring compliance with the documentation content guidance for treatment notes established in the MBPM.

Finally, OIG cites provisions of the Medicare Benefit Policy Manual, IOM Pub 100-2, Chapter 15, Section 220.3.A. This provision (in effect at the time services were rendered) creates a general requirement that documentation must be "legible, relevant and sufficient to justify the services billed." There is also a statement that the documentation requirements of Section 220 establish the "minimal expectations" for documentation content. Consistent with the analysis above, the starred provisions of Section 220.1 in effect at the time services were

rendered and which establish conditions of payment under 42 CFR §424.24(c) and Section 1835(a)(2)(D) of the Act do not require conformance with documentation content guidance for treatment notes found at Section 220.3.E as a condition of payment.

Specific Allegations:

- a. For 93 claims, the OIG alleges that the treatment notes did not indicate the specific interventions/modalities provided.

Response: The basis for this error is that while the notation specifically identified performance of therapeutic exercises to specific regions of the body consistent with the code billed, as required under the MBPM at section 220.3.E, the OIG expressed concern that the documentation did not detail the specific exercises performed. As there is no requirement that the details of how each service was performed, this allegation of error is not supportable. Even if such an instruction did exist, it is not an identified condition of payment under the provisions of section 220.1 and therefore denial of payment is improper.

- b. For 75 claims, the OIG alleges that the treatment notes did not support the number of units billed.

Response: With respect to 71 claims, the OIG alleges that the documentation did not indicate total treatment time. However, the OIG fails to recognize that the total time element of the treatment note documentation only becomes relevant where multiple time-based services are provided and the time in units for each time-based service is not documented. The Medicare Claims Processing Manual (“MCPM”) instruction pertaining to time-based services (IOM Pub 100-4, Chapter 5, Section 20.2.C) references the MBPM instruction (IOM Pub 100-2, Chapter 15, Section 220.3B), which states that “the amount of time for each specific intervention/modality provided to the patient is not required to be documented in the Treatment Note. However, the total number of timed minutes must be documented.” In the documentation provided, the therapist detailed the amount of time spent in performance of each time-based service. As a result, not only can we easily infer the amount of total time spent in the performance of time-based services so that the total time vs. total units analysis indicated in the MCPM can be performed, but the provider exceeded the documentation requirements by detailing the time of performance for each time-based service. As a result, denial of these 71 claims was inappropriate.

With respect to 4 claims, the OIG alleges that the documentation did not justify the number of units reported. It was acknowledged by the provider during the audit that where the time spent performing a time-based service was not expressly recorded, that the service was performed sufficiently to justify a single unit. It is acknowledged, based on the analysis above, that in such a case the total treatment time would have to be documented. Since it was not, the provider acknowledges that the documentation

for these four claims was deficient. Nonetheless, the provider submitted appropriate testimonial evidence demonstrating that services were performed sufficiently to justify the payments made. Under the HHS OIG Office of Audit Services document referenced above, OIG is bound to consider this information. Regardless, this documentation deficiency is not a condition of payment and does not support denial unless the OIG concludes that the documentary and testimonial evidence is insufficient for Medicare to determine the amount or appropriateness of payment.

- c. For 73 claims, the OIG alleges that the treatment notes did not have a valid therapist signature.

Response: Once again, the OIG recognizes that these were electronically created records but nonetheless complains that they were not contemporaneously signed and that the signature stamp applied by the therapist is not a permissible form of signature. As noted above, this is a technical error according to PIM requirements that is not related to an order and therefore is correctable with an attestation. A signature on the treatment note, let alone a contemporaneous signature, is not a condition of payment under the MBPM requirements of Section 220.1. Additionally, compliance is not possible until the note is printed (the EMR program used does not provide for an electronic signature). As such, the therapist's use of his own signature stamp to attest to the fact that the notation was of his own creation (in response to the OIG's request for medical records) certainly meets the spirit of the attestation rule. To the extent that OIG disagrees, the defect is correctable with an attestation and therefore does not serve as a valid basis for denial.

- d. For 7 claims, the OIG alleges that the therapist reported services that were not prescribed under the established plan of care.

Response: There is no evidence that OIG considered whether such a change in plan was appropriate under the provisions for a change in the plan of care outlined in the MBPM at Section 220.1.2.C, which permits written changes to the plan of care. In this case, the changes to the plan of care are evident in the daily notations and where the notation is signed by either the physician/NPP or the physical therapist (in the case of physical therapy). Where the therapist makes a change, the change must not "significantly alter" the plan of treatment. Minor changes in therapeutic modalities used, given that many have similar therapeutic effects despite changes in the physical agent used, would not constitute a major change to the plan of care. As a result, the changes were not significant and denial was improper.

3. 49 of the 100 claims sampled were alleged to be in error because the documentation did not contain a progress report within 10 treatment days or at least once each 30 calendar days, whichever is less (42 claims) or there was no progress report in the medical record (7 claims).

Response: Under Section 220.3B of the MBPM, progress reports are “required” although they are not required as a condition of payment under Section 220.1. For this reason alone, denial of payment is not warranted except where the deficiencies would substantiate a conclusion that services were not medically necessary under the provisions of Section 220.2.

The OIG also apparently failed to consider the provision detailing that progress reports are required only when records are requested after the reports are due, as well as the provision indicating that treatment notes can serve as progress notes where they contain the appropriate information.

The allegation of error also ignores the purpose of progress reports, which CMS expressly declares at Section 220.3D of the MBPM are for justifying the necessity of treatment. The allegation of error is based on perceived content deficiencies of the record as opposed to whether the documentation and clinical circumstances warranting the care provided were consistent with the standards of necessity detailed at Section 220.2 of the MBPM. Therefore, the denials are improper.

Relative to the timing, OIG did recognize in its analysis that there is a 7-day grace period for a delayed report. What it did not evaluate was whether the treatment notes within the appropriate time frame (in cases where a formal progress report was not evident), demonstrated the progress of the patient as well as the active participation of the therapist/clinician. Relative to content, CMS provides the following guidance:

- Assessment of improvement, extent of progress (or lack thereof) toward each goal;
- Plans for continuing treatment, reference to additional evaluation results, and/or treatment plan revisions should be documented in the clinician’s Progress Report; and
- Changes to long or short-term goals, discharge or an updated plan of care that is sent to the physician/NPP for certification of the next interval of treatment.

Relative to the first element, an absence of documented progress can be easily inferred to mean that no progress occurred. In some cases, progress was evident through the subjective and objective data recorded. Similarly, an absence of documentation detailing changes to the plan relative to continuing treatment or plan revisions appropriately indicate that the therapist had no intention of changing the plan of care. As noted in our response above, where minor changes were made, they were evident in the documentation. Additionally, it cannot be ignored that collectively, relative to the purpose of establishing the need for care, these content standards seem to suggest that they are based on the concept that for care to be necessary, the therapist must provide evidence of improvement in the patient’s condition contrary to the conclusions of CMS expressed in the *Jimmo* settlement.

Ultimately, the perceived defects, which are based on an incomplete analysis, do not preclude an analysis of medical necessity. As OIG addressed the necessity of care as a separate allegation of error, the findings associated with these 49 claims do not evidence violation of a condition of payment and denial is improper.

4. 44 of the 100 claims sampled were alleged to be in error because the therapy services were not medically necessary.

Response: In support of its allegation that services were not medically necessary, the OIG has relied on purported documentation deficiencies as follows:

- Goals in plans of care were not measurable (35 services)
- Invalid or missing certifications of the plan of care (35 services)
- Overall medical record documentation failed to support medical necessity (25 services)
- Physical therapy was repetitive with no evidence that skilled therapy services were needed (24 services).

OIG notes review of 43 claims/services by an independent medical review contractor and that the additional claim was reviewed by the Medicare Administrative Contractor. OIG cites section 1862(a)(1)(A) of the Act as the standard for necessity but does not reference the provisions of Section 220.2 of the MBPM.

With respect to the first claimed deficiency, the presumption is that measurable goals are required as a precondition to a determination of medical necessity. As addressed above, this is not the case and even if it were, such a conclusion would be contrary to the determination of CMS in *Jimmo*.

Relative to the second claimed deficiency, a certification of the plan of care by a physician/NPP is a condition of payment unrelated to the necessity of care. Nevertheless, OIG has ignored the provisions on delayed certification in the MBPM at Section 220.1.3, which permits delayed certifications at any later date where the physician/NPP makes a certification that is accompanied by a reason for the delay. As the therapist has since obtained the appropriate certifications, this basis for denial is no longer valid.

With respect to the third claimed deficiency, no specific facts are provided supporting the determination that the “overall medical record failed to support medical necessity.” A review of the spreadsheet data for these claims reveals that in 23 cases, “no objective progress” was indicated as a basis for the determination, which is contrary to CMS disavowing the so called “improvement standard” as a predicate for coverage in the *Jimmo* settlement. Additionally, OIG notes that in 9 cases that the therapy was repetitive with no evidence of skilled therapy services needed. The MBPM describes unskilled services as “palliative” procedures that are repetitive OR reinforce previously learned skills OR maintain function after a maintenance program has developed. There is no evidence that any of the care was purely palliative (i.e. for short term reduction of pain only). There is also no evidence that the modalities and procedures were performed to reinforce previously learned skills. Such an allegation is usually appropriate with occupational therapy techniques designed to teach specific ADL skills, which is not the case for the services evaluated. Finally, the preclusion pertaining to therapy oriented to maintenance of function is contrary to the CMS conclusions pertaining to necessity in the *Jimmo* settlement where it disavowed that CMS ever required

“improvement” as a pre-condition to coverage. Finally, the OIG’s determination that the documentation failed to support medical necessity is called into question by the fact that it made two different determinations on medical necessity for two separate service dates under the same plan of care; the OIG found that services rendered to a patient early on in treatment under a plan of care were not medically necessary, but that services rendered later under the same plan of care were not medically necessary. As a result, the allegations of error, to the extent that they served as a basis for denial under the standards of medical necessity are not supportable.

Finally, for the two remaining cases, OIG alleged in both that “goals were not measurable”, which as noted above is neither a condition of payment nor a valid basis for evaluating the necessity of care. In one of these cases, OIG made the additional allegation and in one of these cases therapy was repetitive with no evidence of skilled therapy services needed. As is noted above, this is an invalid basis for declaring services to be medically unnecessary.

As demonstrated above, the various allegations provided in an attempt to justify that services were not medically necessary for the 44 claims identified are invalid and therefore do not support denial of payment.

5. 39 of the 100 claims sampled were alleged to not meet Medicare’s physician certification requirements.

Response: While it is correct that certifications must be signed and dated, the OIG appears to have ignored the CMS provision that allows delayed certifications. As noted above in response to allegation 4, Section 220.1.3 of the MBPM permits delayed certification at any later date where the physician/NPP makes a certification that is accompanied by a reason for the delay. CMS indicates a variety of reasons including: the physician simply failed to sign and return the certification or that the certification was lost. As the therapist has since obtained the appropriate certifications, this basis for denial is no longer valid.

Response to OIG’s Projected Overpayment

Based on the foregoing findings of alleged error, the OIG has projected overpayment in the amount of \$634,837 and recommends that a refund to the Federal Government be made in that amount. However, we have identified numerous problems in the statistical sampling methodology utilized by the OIG.

The timeframe for the audit included claims from 2011 and excluded unpaid claims and claims with a total paid amount less than \$25.00. While the number of claims that fell into this category is not disclosed, the exclusion of these low value claims from the sample would appear to bias the projected financial error to yield a higher overpayment amount even assuming the basis for error was valid. This conclusion is supported given that the point estimate for the projected overpayment exceeds the total payment amount for the universe of claims.

Relative to the sample size determination, OIG discloses that the sample was a “simple random sample” but does not divulge the basis for determining that the sample size of 100 claims was a statistically valid sample size.

Additionally, there is no estimated error rate, universe amount or standard deviation values provided, which are necessary to determine the appropriate sample size. As a result, it is apparent that the value of 100 claims was arbitrarily selected on the presumption that the sample was appropriately sized. While noted that insufficient sample size is not a per se basis for determining that a projection is invalid, PIM standards do require that the projection be statistically valid. Specifically, CMS requires that “proper procedures for execution of probability sampling...be followed.” IOM Pub 100-8, Chapter 8, Section 8.4.4.3.

The basis for this requirement is fundamental to the theory supporting the validity of statistical error rate prediction. Simply put, where the sample is not representative of the universe, the resulting projection becomes an incalculably invalid estimate of the total error for which selection of the lower bound value cannot compensate.

The non-statistical nature of the projection in this case is evident given that the point estimate from the projection calculations at Appendix B of the draft report yielded an amount in excess of the total value of all claims in the sampling frame strongly suggesting that the sample as drawn was not representative of the universe.

As an additional concern, OIG alleges a variety of errors, some of which apply to the same claim. Assuming the allegations of error justified a denial of payment, which they do not, as there is no normative distribution of a single allegation of error among the samples let alone the permutations created by allegations of a combination of errors, the projection based solely on the presumed financial error in the sample is not a valid basis for predicting the particular error or errors that might be found in the universe of claims.

Finally, the sample numbers contained within the summary of sample errors (Appendix D) do not correlate with the original sample number assignment that was provided in the audit, thereby challenging the validity of random selection.

For these reasons, we believe the projection is not statistically valid.