

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOX REHABILITATION
CLAIMED UNALLOWABLE
MEDICARE
REIMBURSEMENT FOR
OUTPATIENT THERAPY SERVICES**

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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



Why OIG Did This Review

Medicare Part B provides for the coverage of outpatient therapy services, including occupational, physical, and speech therapy. Previous OIG reports identified unallowable claims for these services. Fox Rehabilitation (Fox), headquartered in New Jersey, was among the largest providers of outpatient therapy services in the country.

Our objective was to determine whether claims for outpatient therapy services provided in New Jersey and submitted for Medicare reimbursement by Fox complied with Medicare requirements.

How OIG Did This Review

Our review covered Medicare Part B claims for outpatient therapy services provided by Fox in New Jersey from July 2013 through June 2015, totaling \$39.7 million. We had medical reviewers, consisting of physicians and certified billing professionals, review a random sample of 100 of these claims to determine whether services complied with Medicare medical necessity, documentation, and coding requirements.

Fox Rehabilitation Claimed Unallowable Medicare Reimbursement for Outpatient Therapy Services

What OIG Found

For 85 of the 100 claims in our random sample, Fox improperly claimed Medicare reimbursement for outpatient therapy services. Based on medical review, we determined that all 85 claims had services that were not medically necessary. For nearly all of these claims, the amount, frequency, and duration of services were not reasonable and consistent with acceptable standards of practice. Further, some services did not require the skills of a licensed therapist or were not an effective treatment for the Medicare beneficiary's condition. This occurred because Fox did not follow its policies and procedures to ensure that services complied with Medicare requirements.

On the basis of our sample results, we estimated that Fox improperly received at least \$29.9 million in Medicare reimbursement for services that did not comply with certain Medicare requirements.

What OIG Recommends and Fox Rehabilitation Comments

We recommend that Fox refund \$29.9 million to the Federal Government and ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements.

Fox disagreed with our findings and recommendations, our use of statistical sampling, and our sampling methodology. Fox stated that its internal compliance program ensures that outpatient therapy services are provided and documented in accordance with Medicare requirements. After reviewing Fox's comments, we maintain that our findings and recommendations are valid. We obtained independent medical review of the claims for medical necessity, documentation, and coding errors. Additionally, Federal courts have consistently upheld statistical sampling and estimation as a valid means to determine overpayment amounts in Medicare.

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INTRODUCTION

WHY WE DID THIS REVIEW

Previous Office of Inspector General (OIG) reports identified claims for outpatient therapy services, including occupational, physical, and speech therapy, that were not reasonable, medically necessary, or properly documented. Appendix A contains a list of those related OIG reports. Fox Rehabilitation (Fox) was among the largest providers of outpatient therapy services in the country.

OBJECTIVE

Our objective was to determine whether claims for outpatient therapy services provided in New Jersey and submitted for Medicare reimbursement by Fox complied 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 covers services considered medically necessary to treat a disease or condition, including outpatient therapy services. CMS contracts with Medicare contractors to process and pay Part B claims.

Medicare Part B Outpatient Therapy Services

Medicare Part B provides for the coverage of outpatient therapy services, including occupational, physical, and speech therapy (the Act §§ 1832(a)(2)(C) and 1861(g), (p) and (II)).

Occupational therapy services are designed to improve the ability of mentally, physically, developmentally, or emotionally impaired patients to perform everyday tasks of living and working, with the goal of reestablishing independent, productive, and satisfying lives. Physical therapy services are designed to evaluate and treat disorders of the musculoskeletal system with the goal of improving mobility, relieving pain, and restoring maximal functional independence. Speech therapy services are designed to evaluate, diagnose, and treat speech and language disorders.

For Medicare Part B to cover outpatient therapy services, the services 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.¹ Further, Medicare Part B pays for outpatient therapy services if they are performed by or under the personal supervision of a therapist in private practice.² Finally, the Act precludes payment to any provider of services or other person without the information necessary to determine the amount due the provider.³

Medicare requirements are further clarified in chapter 15 of CMS's *Medicare Benefit Policy Manual* (Pub. No. 100-02) and in chapter 5 of its *Medicare Claims Processing Manual* (Pub. No. 100-04).

Fox Rehabilitation

Fox, headquartered in New Jersey, is a private practice of physical, occupational, and speech therapists who provide services in acute, post-acute, home, senior living community, and outpatient settings. From July 1, 2013, through June 30, 2015 (audit period), Fox claimed reimbursement for outpatient therapy services provided in New Jersey to 15,287 Medicare beneficiaries by 342 therapists.

HOW WE CONDUCTED THIS REVIEW

Our review covered 400,221 outpatient therapy service claims for services that Fox provided in New Jersey with paid amounts of \$20 or more, totaling \$39,738,889, during the 2-year audit period. We reviewed a random sample of 100 claims. We contracted with an independent medical review contractor that reviewed the medical records for the sampled claims to determine whether services were allowable in accordance Medicare's medical necessity, documentation, and coding requirements.⁴

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 contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

¹ The Act §§ 1862(a)(1)(A) and 1835(a)(2)(C) and (D), and 42 CFR § 424.24.

² 42 CFR §§ 410.59, 410.60, and 410.62.

³ The Act § 1833(e).

⁴ The independent medical review contractor's staff included, but was not limited to, physicians and certified billing professionals. In addition, the contractor had quality assurance procedures implemented to ensure all medical review determinations made by its staff were factually accurate, complete, and concise.

FINDINGS

Fox claimed Medicare reimbursement for outpatient therapy services that did not comply with Medicare requirements. Of the 100 claims in our random sample, Fox properly claimed reimbursement for 15 claims. Fox improperly claimed Medicare reimbursement for the remaining 85 claims. Specifically:

- 85 claims included therapy services that were not medically necessary,
- 1 claim did not meet Medicare documentation requirements, and
- 1 claim did not meet Medicare coding requirements.

The total errors exceed 85 because some claims contained more than one error.

These deficiencies occurred because Fox did not follow its policies and procedures to ensure that billed services complied with Medicare requirements.

On the basis of our sample results, we estimated that Fox improperly received at least \$29,902,452 in Medicare reimbursement for outpatient therapy services that did not comply with certain Medicare requirements.⁵

SERVICES NOT MEDICALLY NECESSARY

For services to be payable, a beneficiary must have the need for outpatient therapy services (*Medicare Benefit Policy Manual*, chapter 15, § 220.1). For a service to be covered, the service must be reasonable and necessary (the Act § 1862(a)(1)(A) and *Medicare Benefit Policy Manual*, chapter 15, § 220).

Services are reasonable and necessary if it is determined that, among other things, services were safe and effective, of appropriate duration and frequency within accepted standards of medical practice for the particular diagnosis or treatment, and met the patient's medical needs (*Medicare Program Integrity Manual*, chapter 3, § 3.6.2.2). Additionally, to be considered reasonable and necessary, the service must require the skill of a physical therapist (*Medicare Benefit Policy Manual*, chapter 15, § 220.2.B).

⁵ To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual overpayment total at least 95 percent of the time.

Services need to be provided only when there is an expectation of improvement within a reasonable and predictable period of time. Improvement is demonstrated by successive objective measurements. If an individual's expected rehabilitation potential is insignificant in relation to the extent and duration of therapy services required to achieve that potential, rehabilitative therapy is not reasonable and necessary (Medicare Benefit Policy Manual, chapter 15, § 220.2.C).

For 85 claims, Fox received Medicare reimbursement for services that the beneficiaries' medical records did not support as being medically necessary. The results of the medical review indicated that these services did not meet one or more Medicare requirements.⁶

Care Was Not Appropriate

For 85 claims, the care provided was not appropriate. Specifically, Medicare beneficiaries received services that were not within standards of practice given the diagnoses, complexities, severities, and interaction of their conditions. For example, one Medicare beneficiary with dementia received home visits from a health professional when a home exercise program was more appropriate, given the beneficiary's diagnosis. Medical records indicated that the beneficiary was evaluated as requiring improved motor function to transition to an assisted living facility but also had underlying cognitive issues. The additional walking distance that the beneficiary gained through home visits did not affect her ability to transition to an assisted living facility because of those cognitive issues. The medical review contractor determined that a home exercise program with assistance from the beneficiary's caregivers would have better suited her needs.

Services Were Not Reasonable

For 84 claims, the therapy services were not reasonable. Specifically, the amount, frequency, and duration of the outpatient therapy services were excessive given the beneficiaries' minimal gains. For example, one Medicare beneficiary was initially assessed as only able to walk 50 feet with moderate assistance when she required the ability to walk 200 feet to her assisted living facility's dining and living areas. However, medical records indicated that the beneficiary increased her walking distance to 350 feet with minimal assistance during her second therapy treatment and to over 450 feet with minimal assistance after several more treatments. The medical review contractor determined that the number of treatments that the beneficiary received was excessive.

Services Were Not Specific or Effective

For 26 claims, the therapy services were not specific to or effective for the condition of the beneficiary. For example, a Medicare beneficiary had a history of injuries and pain, and caregivers reported increased difficulty in providing care. In addition, the beneficiary had

⁶ The total errors exceed 85 because each claim contained more than 1 deficiency.

limiting factors, such as behavioral issues, and was able but unwilling to perform certain activities of daily living. The medical records did not show functional improvements after the occupational therapy or how occupational therapy benefited the beneficiary's condition. Based on the medical records, the medical review contractor determined that a behavioral and maintenance exercise program, guided by the beneficiary's caregivers, would have been the specific and potentially more effective treatment than occupational therapy.

No Expectation of Significant Improvement

For 16 claims, the therapy services did not contribute to the beneficiary's improvement. In one example, based on the medical records, the medical review contractor determined there was no significant improvement in the beneficiary's condition to warrant further therapy.

Services Did Not Require the Skills of a Therapist

For five claims, the therapy services did not require the skills of a therapist. For example, one Medicare beneficiary was living with a family member and had part-time caregiver assistance when the therapy treatment started. There was no new injury or impairing condition, and the beneficiary continued to require only minimal assistance. The beneficiary was receiving treatments that could have been provided through a home exercise program with family assistance that did not require the skills or supervision of a therapist.

DOCUMENTATION DID NOT MEET MEDICARE REQUIREMENTS

Medicare contractors shall determine the necessity of services based on the delivery of services as directed in the beneficiary's plan and as documented in the treatment notes and progress report. The progress report provides justification for the medical necessity of the treatment. The minimum progress report period shall be at least once every 10 treatment days. If the clinician has not written a progress report before the end of the progress report period, it shall be written within 7 calendar days after the end of the reporting period (*Medicare Benefit Policy Manual*, chapter 15, § 220.3D).

For one claim, Fox received Medicare reimbursement for which the medical record indicated that the progress report was not prepared within the minimum progress report period or within 7 calendar days after the end of the reporting period.

CODING DID NOT MEET MEDICARE REQUIREMENTS

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).

For one claim, Fox billed Medicare with an incorrect Healthcare Common Procedure Coding System (HCPCS) code⁷ that resulted in an overpayment. Specifically, Fox billed Medicare for therapeutic activity (HCPCS code 97530) when it should have billed for self-care management training (HCPCS code 97535). The reimbursement amount was higher for therapeutic activity than it was for performing self-care management training; however, we did not calculate the overpayment difference because this claim contained more than one error and was entirely unallowable.

RECOMMENDATIONS

We recommend that Fox:

- refund \$29,902,452 to the Federal Government and
- ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements.

FOX REHABILITATION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Fox, through its attorneys, did not concur with our recommendations and stated that its internal compliance program ensures that outpatient therapy services are provided and documented in accordance with Medicare requirements. Specifically, for the 85 claims that we found to not be in compliance with Medicare requirements, Fox contested and objected to our findings that it (1) submitted claims to Medicare that were medically unnecessary and (2) did not meet documentation and coding requirements. In addition, Fox stated that it was improper for us to use statistical sampling in our review.

After reviewing Fox's comments, we maintain that our findings and recommendations are valid. Regarding Fox's disagreement with our determination that it claimed Medicare reimbursement for outpatient therapy services that did not comply with Medicare requirements, we note that we obtained independent medical review of our sample claims for medical necessity, documentation, and coding errors. Regarding our use of statistical sampling, Federal courts have consistently upheld statistical sampling and extrapolation as a valid method to determine overpayment amounts in Medicare.

Fox's comments are included as Appendix E. Fox also provided additional documentation, including (1) the results of its own review of the 85 claims that we questioned, (2) an independent medical expert's report on 22 of these claims, and (3) a statistician's report on our

⁷ The health care industry uses HCPCS codes to standardize coding for medical procedures, services, products, and supplies.

sampling methodology. We did not include the additional documentation because it was voluminous and contained personally identifiable information.⁸

MEDICAL NECESSITY

Fox Rehabilitation Comments

Fox provided a rebuttal for each of the 85 claims that we questioned in our draft report and, for 22 of these claims, also provided a rebuttal prepared by an independent medical expert.⁹

In its comments, Fox stated that it disagreed with our medical review contractor's determinations regarding medical necessity. Specifically, Fox stated that, for the claims that we determined not to be reasonable, we relied on an "improvement standard" that violates Medicare regulations and a Federal court order. According to Fox, the "improvement standard" requires patients to have significant improvement or an expectation of significant improvement within a reasonable and predictable period of time from the therapy services. However, according to Fox, there is no legal requirement that beneficiaries make any gains, let alone minimal gains. Fox stated that we improperly failed to consider that beneficiaries are entitled to skilled maintenance therapy under certain circumstances. Fox asserted it provided skilled maintenance therapy services that were necessary for beneficiaries to maintain or prevent the decline of their functions. Fox stated that the judgment of a beneficiary's treating physician should determine whether a beneficiary has the potential to benefit from therapy and that certification of a beneficiary's plan of care by the physician is a determination of medical necessity of the amount, frequency, and duration of services provided.¹⁰ Further, according to Fox, we did not afford extra weight to the treating physicians' determinations.

Fox stated that it complied with local guidelines regarding the amount and frequency of services¹¹ and that its care was specific, effective, skilled, and appropriate. In addition, Fox's medical expert concluded that all 22 of the claims he reviewed were medically necessary and that the amount, frequency, and duration of the services were reasonable and met or exceeded acceptable standards of practice. The medical expert further stated that all of the services he reviewed required the skills of a licensed therapist. As such, the treatments were effective, specific, and appropriate for the associated beneficiaries' conditions.

⁸ We are separately providing Fox's additional documentation to CMS.

⁹ We did not include the medical expert's rebuttals as part of Fox's comments because Fox considered them separate from its formal comments on our draft report and they contained personally identifiable information.

¹⁰ Specifically, Fox stated that the treating physician (1) determines the beneficiary's potential to benefit from therapy, (2) certifies the beneficiary's plan of care, and (3) personally observes and examines the beneficiary. Therefore, according to Fox, the treating physician is in the best position to determine if the beneficiary would benefit from therapy.

¹¹ In addition to citing local guidelines, Fox also cited medical literature in its comments.

In addition, Fox cited section 1879 of the Act, which states that if a service is denied based on a finding that it is not reasonable and necessary, liability for the noncovered service may be limited if the provider or practitioner did not know, and could not have been reasonably expected to know, that the service would not be covered.

Office of Inspector General Response

We obtained an independent medical review of the sampled claims for medical necessity and documentation and coding requirements, and our report reflects the results of that review. The independent contractor had no affiliation with the U.S. Department of Health and Human Services, OIG, the associated beneficiaries, or Fox. The contractor's medical reviewers were board-certified in physical medicine and rehabilitation. The reviewers examined all of the medical records and documentation that Fox submitted and carefully considered this information to determine whether claims for outpatient therapy services provided by Fox complied with Medicare requirements.¹² On the basis of the independent contractor's conclusions, we determined that Fox improperly claimed Medicare reimbursement for 85 claims. We continue to stand by those determinations.

Regarding Fox's assertion that liability for the noncovered service may be limited due to section 1879 of the Act, both the regulations at 42 CFR § 411.406 and the guidelines in the *Medicare Claims Processing Manual*, chapter 30 § 40.1, explain that evidence that the provider did in fact know or should have known that Medicare would not pay for a service or item includes Medicare's general notices to the medical community of Medicare payment denial of services and items under all or certain circumstances. These notices include, but are not limited to, manual instructions such as the Medicare manual provisions cited in this report.

DOCUMENTATION AND CODING REQUIREMENTS

Fox Rehabilitation Comments

Fox stated that we denied one claim based on an outdated and incorrect legal requirement concerning the minimum progress report period. Fox also stated that we incorrectly claimed that it improperly billed one other claim under the wrong HCPCS code.

Office of Inspector General Response

We acknowledge that the language concerning the minimum progress report requirement was updated during the time of our audit period and we have revised our report accordingly. However, we referenced the correct requirement and maintain that the minimum progress

¹² As part of the independent contractor's review, reviewers examined the beneficiary's medical record to determine whether (1) there was an expectation for significant improvement within a reasonable and predictable period of time or (2) care was necessary for safe and effective maintenance of the beneficiary's condition.

report frequency was still not met.^{13, 14} Regarding the claim for which we determined that Fox applied the wrong HCPCS code, we relied on our independent medical review contractor to determine the appropriate billing code.

SAMPLING METHODOLOGY

Fox Rehabilitation Comments

Fox stated that the Act limits our use of extrapolation because certain conditions were not met; therefore, it was improper for us to use it in our review.¹⁵ In addition, Fox contracted a statistician to review our sampling methodology and provided a report by the statistician along with its comments.¹⁶ According to the statistician, our sample of 100 claims did not pass the test for randomness or statistical significance and, therefore, was not statistically valid. The statistician further stated that our extrapolation was “fatally flawed.”

Specifically, the statistician stated that our sample design was not properly executed in accordance with CMS guidelines. Further, the statistician stated that we failed to provide adequate documentation to support or explain our methods for (1) choosing our sample size; (2) choosing the claims we sampled; (3) calculating the point estimate and precision levels; and (4) extrapolation, in general. The statistician also stated that we did not stratify our sample claims, thereby introducing “high variability and an obvious bias” into our calculations. The statistician further stated that our 100 sample claims and the associated extrapolation were not representative of the sample frame from which the claims were drawn. The statistician also took issue with our including outlier claims in our sample frame and sample, and described this as a “fatally flawed approach,” based on CMS guidelines and standards of statistical practice.

Office of Inspector General Response

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.¹⁷ The legal standard for use of sampling and

¹³ *Medicare Benefit Policy Manual*, chapter 15, § 220.3D.

¹⁴ In addition to not meeting the minimum progress reporting frequency, this claim contained other deficiencies.

¹⁵ Specifically, Fox asserted that we did not demonstrate that it had a sustained or high level of payment error based on its assumption that all 85 claims we found to be in error were, in fact, allowable.

¹⁶ We did not include the statistician’s report as part of Fox’s comments because Fox considered it to be separate from Fox’s formal comments on our draft report and it contained personally identifiable information.

¹⁷ See *Momentum EMS, Inc. v. Sebelius*, 2014 WL 199061 at *9 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.¹⁸

We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant Medicare requirements in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Our extrapolation was restricted to the sampling frame from which our statistical sample was drawn. We did not use our sample results to estimate any overpayments associated with items that were outside of our frame (e.g., claims less than 20 dollars).¹⁹

We maintain that our sample of 100 claims was representative of the sampling frame, as these claims were randomly selected from a sampling frame of 400,221 claims submitted by Fox for Medicare reimbursement. In regards to outlier claims, we maintain that these claims were actually submitted by Fox for Medicare reimbursement and, therefore, should not have been excluded from our sample frame, as the statistician implied.

By recommending recovery for our audit at the lower limit of a 90-percent confidence interval, we account for the sample size, the universe size, and the overall precision in a manner that is favorable to Fox. In fact, if we had used a larger, more precise sample, the expected result would be a higher lower limit and thus a higher recommended refund.

OTHER MATTERS: PLANS OF CARE NOT CERTIFIED IN A TIMELY MANNER

Federal regulations require physicians to certify plans in a timely manner, unless there are legitimate reasons for delaying the certifications. However, CMS guidance may allow certifications to be delayed even when there is not a legitimate reason for the delay. This may allow beneficiaries to receive outpatient therapy services before a physician certifies the services.

Initial certifications must be obtained as soon as possible after a 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)).²⁰ Initial certification requirements are satisfied by a physician or nonphysician practitioner's certification of the initial plan. For an

¹⁸ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

¹⁹ We note that we provided Fox with the Access database from which we drew our sample claims, as well as our statistical outputs from RAT-STATS. An explanation of our statistical sampling methodology (Appendix C) was included as part of our draft report to Fox.

²⁰ Physician certification is documented by a dated signature or verbal order (*Medicare Benefit Policy Manual*, chapter 15, § 220.1.3.B).

initial plan to be certified in a timely manner, the physician or nonphysician practitioner must certify the initial plan as soon as it is received or within 30 days of the initial treatment. For recertification, the plan must be dated during the duration of the initial plan or within 90 calendar days of the initial treatment under that plan, whichever is less (*Medicare Benefit Policy Manual*, chapter 15, §§ 220.1.3.B, C and D).

CMS policy permits delayed certification and recertification when, at any later date, a physician or nonphysician practitioner makes a certification accompanied by a reason for the delay and “include[s] any evidence the provider ... considers necessary to justify the delay” (*Medicare Benefit Policy Manual*, chapter 15, § 220.1.3.D). Federal regulations state that delayed certification and recertification statements are “acceptable when there is a legitimate reason for delay” and “must include an explanation of the reasons for the delay” (42 CFR § 424.11(d)(3)).

For 29 claims, Fox did not obtain timely certifications for plans. Specifically:

- for 25 claims, plans were not certified by a physician or nonphysician practitioner within 30 days of the first treatment and
- for 4 claims, plans were not recertified within 90 days of initiation of treatment under that plan.

For example, Fox received payment for outpatient therapy services provided to an 89-year-old Medicare beneficiary who did not have a plan that was certified in a timely manner by a physician or nonphysician practitioner. Specifically, a physical therapist working for Fox established an initial plan for the beneficiary in June 2014, but the beneficiary’s referring physician did not certify the plan until May 2015. The medical record did not contain a justification for the delayed certification.

CMS may permit delayed certification even when there is not a legitimate reason for the delay. Whereas Federal regulations state that delayed certification and recertification statements are acceptable when there is “a legitimate reason” for delay, CMS’s *Medicare Benefit Policy Manual* states that providers “should include any evidence ... necessary to justify the delay.” The *Medicare Benefit Policy Manual* does not indicate what constitutes a legitimate reason for a delay and, furthermore, indicates that delayed certifications may be acceptable if the only problem is that they were not signed. The *Medicare Benefit Policy Manual* provides the following example: “[A] certification may be delayed because the physician did not sign it, or the original was lost.”

Therefore, we are not questioning sample claims for which Fox obtained delayed certification or recertification.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>A Missouri Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Physical Therapy Services</i>	<u>A-07-14-01147</u>	05/05/2017
<i>A Southern California Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services</i>	<u>A-09-15-02015</u>	12/27/2016
<i>A Northern California Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services</i>	<u>A-09-14-02040</u>	11/01/2016
<i>A Kansas Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Physical Therapy Services</i>	<u>A-07-14-01146</u>	08/22/2016
<i>A Florida Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services</i>	<u>A-04-15-07054</u>	06/30/2016
<i>A South Texas Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Physical Therapy Services</i>	<u>A-06-14-00064</u>	06/14/2016
<i>A Florida Physical Therapy Practice Claimed Unallowable Medicare Part B Reimbursement for Some Outpatient Therapy Services</i>	<u>A-04-15-07055</u>	04/22/2016
<i>A Texas Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services</i>	<u>A-06-14-00065</u>	03/17/2016
<i>Boulevard Health Care, Inc., Improperly Claimed Medicare Reimbursement for Outpatient Physical Therapy Services</i>	<u>A-02-14-01004</u>	10/29/2015
<i>AgeWell Physical Therapy & Wellness, P.C., Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services</i>	<u>A-02-13-01031</u>	06/15/2015
<i>An Illinois Physical Therapist Claimed Unallowable Medicare Part B Reimbursement for Outpatient Therapy Services</i>	<u>A-05-13-00010</u>	08/20/2014

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered Medicare outpatient therapy claims for services provided in New Jersey by Fox during the period July 1, 2013, through June 30, 2015, with paid amounts of \$20 or more. Our sampling frame consisted of 400,221 claims for outpatient therapy services, totaling \$39,738,889, of which we reviewed a sample of 100 claims. These claims were extracted from CMS's National Claims History (NCH) file.

We limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of Fox'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 from the NCH file, but we did not assess the completeness of the file.

We performed fieldwork from December 2015 through October 2016.

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 Fox officials to gain an understanding of Fox's policies and procedures related to providing and billing Medicare for outpatient therapy services;
- extracted from CMS's NCH file a sampling frame of 400,221 outpatient therapy service claims with paid amounts of \$20 or more, totaling \$39,738,889, for services provided in New Jersey by Fox during our audit period;
- searched a CMS database to identify whether any claims in our sampling frame were under review or had been reviewed and then suppressed²¹ all nonreviewed claims;
- selected a random sample of 100 claims for outpatient therapy services from the sampling frame;

²¹ We identified in the CMS database that all claims in our sampling frame were under our review. Therefore, they should not have been reviewed separately.

- obtained medical records and other supporting documentation from Fox for the 100 sampled claims;
- used an independent medical review contractor to review medical records and other documentation to determine whether services provided were allowable in accordance with Medicare medical necessity, documentation, and coding requirements;
- estimated the unallowable Medicare reimbursement paid in the sampling frame of 400,221 claims; and
- discussed the results of our review with Fox officials.

See Appendix C for the details of our statistical sampling methodology and Appendix D for our sample results and estimates.

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 C: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The population consisted of all Medicare Part B claims for outpatient therapy services provided by Fox in New Jersey from July 1, 2013, through June 30, 2015, with paid amounts of \$20 or more.

SAMPLING FRAME

The sampling frame was an Access database containing 400,221²² claims for outpatient therapy services, totaling \$39,738,889, provided by Fox in New Jersey during the audit period with paid amounts of \$20 or more. The claims data were extracted from the CMS NCH file.

SAMPLE UNIT

The sample unit was an outpatient therapy service claim.

SAMPLE DESIGN

We used a simple random sample.

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 (RAT-STATS).

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.

ESTIMATION METHODOLOGY

We used the OAS statistical software, RAT-STATS, to appraise the sample results. We estimated the total amount of inappropriate Medicare payments for unallowable outpatient therapy services made to Fox at the lower limit of the two-sided 90-percent confidence interval.

²² We removed five claims from the sampling frame that were under review (see fifth bullet under “Methodology” in previous appendix).

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Claims in Frame	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Claims	Value of Unallowable Claims
400,221	\$39,738,889	100	\$9,871	85	\$8,160

Estimated Value of Unallowable Claims
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$32,656,273
Lower limit	29,902,452
Upper limit	35,410,094

APPENDIX E: FOX REHABILITATION COMMENTS

FOX REHABILITATION

Response to the Draft Report of the Office of Inspector General

Report Number: A-02-16-01004

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Fox Rehabilitation Services, Inc. (“Fox”) submits the following memorandum in opposition to the Office of Inspector General’s (“OIG”) audit findings in the OIG’s draft report dated April 11, 2017.

I. INTRODUCTION

Fox provides physical, occupational, and speech therapy to geriatric patients, many of whom are chronically ill and/or have multiple co-morbidities, Alzheimer’s disease, and/or dementia. Although the average Medicare beneficiary is 76 years old, and only 32% of Medicare beneficiaries have three or more chronic conditions, the average age of Fox’s patients is 83, and 77% of Fox’s patients have three or more chronic conditions. The frail nature of Fox’s patient population requires Fox to provide skilled care, under a physician’s supervision, as recognized by the Centers for Medicare & Medicaid Services’ (“CMS”) own recent studies which show that “[a]nual per-beneficiary Medicare payments for PT, OT, and SLP services generally increase with age.” Additionally, data indicates that beneficiaries with multiple chronic conditions account for a disproportionate share of Medicare spending.¹

In order to meet the special needs of its unique patients, upon referral from the patient’s treating physician, Fox performs a comprehensive geriatric assessment of each patient and develops an individual plan of care for each patient. Consistent with Medicare requirements, the patient’s treating physician determines that the patient needs the specified therapy services by certifying the plan of care. Then, pursuant to the certified plan of care, patients are treated by licensed practitioners in order to avoid unwanted complications that would require more expensive and intensive hospitalizations. The frequency of treatment sessions depends on the individualized needs of each patient as set forth in the plan of care.

Thus, by treating all patients in accordance with certified plans of care, Fox relies on the clinical judgment of the patients’ treating physicians, as well as its professional therapists, that the services provided are medically reasonable and necessary. Fox clinicians request that the treating physicians recertify the plans of care only if the clinicians determine that further services would be skilled, reasonable, and necessary. By providing services pursuant to re-certified plans of care, Fox clinicians continue to rely on the treating physicians’ determinations that additional care is skilled and medically necessary. In its findings, however, the OIG failed to follow the legal requirement that it give “extra weight” to the findings of the treating physicians when reviewing the claims at issue, or otherwise supply a “reasoned basis for declining to do so.”

Skilled therapy services are especially necessary because of the frail nature of Fox’s patient population and the safety concerns presented in such patients, as well as the fact that most Fox patients suffer from multiple co-morbidities, the interaction of which requires the skill of a therapist to effectively treat. When analyzing the need for skilled therapy, and contrary to the OIG’s explicit findings, the law forbids the OIG from denying coverage simply because a beneficiary lacks “improvement potential” or had impairments that did not “significantly”

¹ Centers for Medicare & Medicaid Services, *Chronic Conditions Among Medicare Beneficiaries Chartbook*, 24 (2012).

improve. An individualized assessment of the beneficiary's medical condition is required, and even if the patient has no potential for improvement or has not demonstrated improvement, the patient is legally entitled to maintenance treatment that prevents or slows further deterioration of a clinical condition.

It is only through Fox's care coordination with treating physicians, comprehensive assessments, and individualized treatment of patients that Fox can effectively meet the healthcare needs of its patient population and prevent the need for additional, more costly healthcare services. This unique nature of Fox's patient population—which often necessitates more extensive skilled care in order to address its specific medical needs and potentially reduce more costly services—was not considered by the OIG.

In providing and billing for these services, Fox's clinicians consistently follow not only CMS' guidelines, but also the internal policies and procedures that Fox has implemented to ensure compliance with Medicare requirements. These policies are enforced through Fox's Compliance Program, which meets the requirements of the Sentencing Guidelines and has been reviewed by counsel on more than one occasion. The Compliance Department is overseen by Fox's Compliance Officer, and it includes a hotline to report concerns, as well as extensive employee compliance training and documentation audits.

In addition to the arguments below,² attached hereto are appendices in which Fox substantively addresses each of the 85 claims that the OIG alleged should be denied. Dr. John H. Fullerton, an independent expert in geriatric medicine, reviewed a sample of 22 patient files; found that the OIG improperly denied coverage for all 22 cases; and prepared specific factual rebuttals for those cases on Fox's behalf. *See* Appendix A. Fox also prepared specific factual rebuttals for all 85 cases. *See* Appendix B. Fox incorporates the appended arguments herein by reference. As these appendices and the below arguments show, the findings and conclusions of the auditors are incorrect for the 85 claims at issue because: (1) the OIG's reliance on the "Improvement Standard" to deny coverage is contrary to law; (2) the OIG's denials improperly contradict the findings of the patients' treating physicians; (3) the amount, frequency, and duration of services were consistent with the standards of practice; and (4) care was specific, effective, skilled, and appropriate.

² Apart from the arguments below, Fox noted factual errors in at least 11 cases contained within the "Rationale" section of the OIG's draft spreadsheet. By way of example only, in the case of patient number 51, the OIG incorrectly claimed that on January 30, 2014, "[t]he patient's pain scores were unchanged over the previous three assessments." On January 30, the patient's pain was rated as 0 at rest and 4 with activity; however, on the three prior visits, her pain was rated as 0 at rest and 5 with activity. Thus, contrary to the OIG's claim, on January 30, the patient's pain did change from the previous three assessments. Another example of an OIG factual error occurred in the case of patient number 37, when the OIG claimed that "[a]s of 1/15/2015, the patient was able to transfer and ambulate 75 feet with a rolling walker and standby assistance." There was no service provided to the patient on January 15, 2015. While the OIG may have intended to reference January 14, 2015, the patient required minimum assistance on that date, not standby assistance. Factual errors in the OIG's "Rationale" for at least 11 denied cases—nearly 15% of the denied cases—undermines the reliability and accuracy OIG's audit findings.

Finally, Frank Cohen, an independent statistical expert, determined that the OIG's method of extrapolation was critically flawed. Mr. Cohen's report is attached hereto as Appendix C and his arguments are incorporated herein by reference.

II. STATEMENTS OF NONOCCURRENCE

- 1) Fox does not concur with the OIG's recommendation that Fox refund \$29,902,452 to the Federal Government. The remainder of this response, including the appendices and exhibits attached hereto, sets forth the reasons why Fox does not concur.
- 2) Fox also does not concur with the OIG's recommendation that Fox ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements. Fox does not concur with this recommendation because Fox's robust Compliance Department ensures that outpatient therapy services are provided and documented in accordance with Medicare requirements.

Although the OIG claimed that the 85 claims were not medically necessary because Fox failed to follow its own policies and procedures to ensure that services complied with Medicare requirements, the OIG did not identify which policies and procedures Fox allegedly failed to follow. Contrary to the OIG's bald claim, Fox's clinicians consistently follow the internal policies and procedures that Fox has implemented to assure the appropriate quality of patient care and accurate billing for services. These policies are enforced through Fox's Compliance Department.

The OIG has presented no evidence of any shortcomings within Fox's Compliance Department. Accordingly, Fox does not concur with the OIG's recommendation that Fox ensure that outpatient therapy services are provided and documented in accordance with Medicare requirements.

III. ARGUMENT

A. *“NO EXPECTATION OF SIGNIFICANT IMPROVEMENT.” THE OIG IMPROPERLY FOUND THAT FOR 16 CLAIMS, THE SERVICES “DID NOT CONTRIBUTE TO THE BENEFICIARY’S IMPROVEMENT” SUCH THAT THERE WAS “NO SIGNIFICANT IMPROVEMENT IN THE BENEFICIARY’S CONDITION TO WARRANT FURTHER THERAPY,”³ AND IN 84 CLAIMS, THE OIG IMPROPERLY FOUND THAT THE SERVICES WERE “EXCESSIVE GIVEN THE BENEFICIARIES’ MINIMAL GAINS.”*

- 1) The OIG’s Reliance On A Lack Of “Significant Improvement” To Deny Coverage Is Contrary To Law.

The OIG impermissibly relied on the “Improvement Standard,” a requirement that a patient have “significant improvement” or an expectation of significant improvement within a reasonable and predictable period of time from the therapy services. This “Improvement Standard,” in whatever form, is an illegal condition of coverage that violates Medicare regulations as well as an existing Federal Court Order. It also prejudices Fox’s patients by denying coverage to the geriatric community, as if geriatric patients with co-morbidities cannot benefit from therapy services.

Under the Medicare statute and regulations, coverage is available for healthcare and therapy services that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” See 42 U.S.C. § 1395y(a)(1)(A). Specifically, outpatient therapy services are covered if the patient’s treating physician certifies that the patient “needs” therapy services by certifying the plan of care. See 42 CFR § 424.24; Medicare Benefit Policy Manual (“MBPM”), Chapter 15, § 220.1.⁴ Fox clinicians provide services pursuant to the certified plan of care and Fox clinicians, therefore, carry out treatment with the expectation of meeting the needs of the patient.

Critically, the MBPM expressly rejects the OIG’s “Improvement Standard.” Per CMS, “Medicare coverage does not turn on the presence or absence of a beneficiary’s potential for improvement from the therapy, but rather on the beneficiary’s need for skilled care.” MBPM, Chapter 15, § 220.2(B). Instead, “[s]killed therapy services may be necessary to improve a patient’s current condition, to maintain the patient’s current condition, or to prevent or slow further deterioration of the patient’s condition. *Id.* at § 220.2(A) (emphasis added).

³ In the OIG’s draft spreadsheet, it similarly claimed that “[t]here was no expectation of significant improvement within a reasonable and predictable period of time, OR care was not necessary for safe and effective maintenance program” in these 16 cases. Regardless of how the OIG articulates this basis of denial, the 16 claims should not be denied for the reasons set forth herein.

⁴ Manuals issued by CMS provide guidance in the administration of the Medicare program. *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 101-02 (1995) (finding that agency manual section is valid interpretive rule and it is reasonable for agency to follow it).

Additionally, outpatient therapy services are covered even if full or partial recovery is not possible. *Id.* at § 220.2(C).⁵

Not only does the OIG's use of an "Improvement Standard" violate the MBPM, it also violates the letter and spirit of an existing Federal Court Order. In January 2011, six Medicare beneficiaries and seven national organizations filed a class action suit, *Jimmo v. Sebelius*, in the District of Vermont against the Secretary of Health and Human Services (the "Secretary"). The *Jimmo* plaintiffs alleged that the Secretary imposed an "Improvement Standard," whereby coverage for certain home healthcare services was denied if a beneficiary's condition had not improved, was unlikely to improve, or in retrospect failed to improve, even when the patient needed skilled care to maintain his or her condition or prevent or slow further deterioration. The Secretary eventually agreed to settle the plaintiffs' claims in accordance with the terms and conditions of a settlement agreement (the "Settlement"), which the Court approved in an Order and incorporated into a judgment.

Pursuant to the Court-ordered Settlement, the parties agreed to a "maintenance coverage standard," which provides that services would be covered if necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care. The parties agreed to implement the maintenance coverage standard in two ways. First, the Order required the Secretary to make it clear that there is coverage for outpatient therapy services when a patient has no restoration or improvement potential, but when that patient needs skilled services, and coverage does not turn on an individual's potential for improvement, but rather on the beneficiary's need for skilled care. Second, the Order required the Secretary to engage in certain educational activities designed to implement the clarifications and to educate stakeholders regarding the maintenance coverage standard. A copy of the Order and the Settlement it incorporates is attached hereto as Exhibit 1.

Recently, the *Jimmo* plaintiffs filed a Motion for Resolution of Noncompliance with the Settlement Agreement, claiming that the Secretary failed to make necessary revisions to the MBPM and that the educational campaign was deficient. On August 17, 2016, the Court granted in part and denied in part the Motion, holding that:

the Secretary failed to fulfill the letter and spirit of the Settlement Agreement with respect to at least one essential component of the Educational Campaign. Plaintiffs have provided persuasive evidence that at least some of the information provided by the Secretary in the Educational Campaign was inaccurate, nonresponsive, and failed to reflect the maintenance coverage standard.

⁵ Similarly, in context of post-hospital skilled nursing care, "[t]he restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities." 42 CFR § 409.32(c).

The Court noted that the plaintiffs had relied upon a number of adverse Qualified Independent Contractor coverage decisions that they contended demonstrated that the “Improvement Standard” still persists. The Court also noted that the plaintiffs submitted a declaration from a retired Administrative Law Judge from the Office of Medicare Hearings and Appeals who averred that the “Improvement Standard” was reflected in decisions appealed to him even after the Settlement became effective and that the Secretary paid only lip service to *Jimmo* without effectively implementing the letter or spirit of the Settlement.

Here, the auditors expressly rely on the illegal “Improvement Standard” in 16 cases:

[f]or 16 claims, the therapy services did not contribute to the beneficiary’s improvement. For example, based on the medical records, the medical review contractor determined there was no significant improvement in the beneficiary’s condition to warrant further therapy.

The rationale in the OIG’s draft report for claiming that services are not medically necessary when there is no expectation of improvement is that “[s]ervices need to be provided only when there is an expectation of improvement within a reasonable and predictable period of time.” This rationale is expressly prohibited by *Jimmo* and the MBPM.

Moreover, in the OIG’s draft report, it claimed that in 84 of the 85 cases, “the amount, frequency, and duration of the outpatient therapy services . . . were excessive *given the beneficiaries’ minimal gains.*” (emphasis added). The OIG’s focus on patients’ “minimal gains” in denying coverage is nothing more than an improper reliance on the “Improvement Standard.” In other words, the OIG is claiming that the patients had insufficient gains in improving their conditions to justify further therapy, which is not only arbitrary, but expressly violates the law. The draft report’s reliance on the illegal “Improvement Standard” in all but one of the denied claims taints the OIG’s audit conclusions in their entirety.

The use of this illegal “Improvement Standard” especially impacts Fox’s patients, who suffer from multiple co-morbidities and/or chronic conditions. As their health deteriorates, their need for physical, occupational, and speech therapies increases. Skilled care is critical to slow their disease process and to maintain their functional ability, yet these are precisely the patients for whom OIG has denied coverage under the “Improvement Standard.”⁶

⁶ CMS advises that “[i]f an individual’s expected rehabilitation potential is insignificant in relation to the extent and duration of therapy services required to achieve such potential, rehabilitative therapy is not reasonable and necessary,” but this statement does not require improvement. MBPM, Chapter 15, § 220.2(C). Although the OIG cited this standard in its argument that improvement is required, “rehabilitation potential” must be construed to include the potential to maintain or prevent the decline of a patient’s condition. Further, CMS provides no guidance about what it considers to be “insignificant” rehabilitation potential or what it considers to be a reasonable extent and duration of therapy services. Given the lack of guidance regarding this statement, as well as the fact that any requirement that a patient show improvement would conflict with other provisions of the MBPM and the *Jimmo* Settlement, which expressly reject the “Improvement Standard,” the OIG cannot rely upon it as a basis for denial of claims merely when there is no improvement or expectation thereof.

In the OIG's draft report, it referenced the care provided to patient number 7 as an example of services that were excessive given the beneficiary's minimal gains. This violates the "Improvement Standard," as explained above. Further, the medical record undermines the OIG's allegation that the patient made only minimal gains. Her transfers went from moderate assistance to standby assistance. On the Chair Rise Test, which measures lower extremity functional strength and serves as an indicator of fall risk, she went from 20 seconds to 18 seconds. Her Arm Curl Test went from zero reps in 30 seconds for right and left to 7 reps in 30 seconds for right and left. On August 13, 2013, the patient ambulated 450 feet with standby assistance, and on August 21, 2013, she ambulated 800 feet with moderate assistance because she was ambulating on uneven surfaces. At evaluation, she required minimum physical and verbal assistance with toileting, but on July 25, 2013, she required only minimal cues and no physical assistance, and on August 29, 2013, she required only standby assistance. Regarding grooming, at the patient's evaluation, she required minimal physical and verbal assistance, but at discharge, she required only minimal cues and no physical assistance. Finally, at evaluation, the patient required minimal physical and verbal assistance with dressing, but on August 5, 2013, she required only minimal cues without physical assistance, and on August 28, 2013, she required only standby assistance.

While the OIG may characterize these gains as "minimal," there is no legal requirement that beneficiaries make "any" gains, let alone "minimal" gains. Further, these gains show that skilled therapy prevented declines in the patient's functional activity, which is sufficient for coverage.

In sum, and for the reasons more fully set forth in Exhibit 2 hereto, the OIG improperly denied coverage to patient number 7. Moreover, as a matter of law, the OIG cannot rely on any form of the "Improvement Standard" as a basis to deny claims, and the OIG's findings must be rejected as contrary to law due to its use of the "Improvement Standard" in 84 of the 85 claims.

- 2) The OIG's Claim That There Was "No Significant Improvement" Or "Expectation Of Significant Improvement" Directly Conflicts With The Judgment Of The Patients' Treating Physicians And The Fox Clinicians Who Evaluated The Patients' Rehabilitation Potential.

A patient's potential to benefit from therapy is indicated on the therapy plan of care as the patient's "rehab potential." The patient's "rehab potential" does not refer to the potential for improvement (as improvement is not a condition of coverage); rather, it refers to whether therapy would benefit the patient. The benefit could include an improvement in the patient's condition or it could refer to maintenance of the patient's condition or prevention of a decline in the patient's condition. The Fox clinicians found the patients' "rehab potential" to be "excellent" in 14 of the denied claims, and they found it to be "good" in 69 of the denied claims.

Fox patients are under the care of the treating physicians who certify the plans of care. In certifying the plans of care, the patients' treating physicians agreed with the clinicians that these 83 patients had a "good" or "excellent" potential to benefit from therapy. The patient's treating physician personally observes and examines the patient. The treating physician is familiar with

the patient's condition(s). Thus, the treating physician is in the best position to determine if the patient would benefit from therapy due to the patient's age, condition(s), and medical complications, as well as the safety concerns at issue.

Notably, all of the treating physicians who certify plans of care for Fox are independent. They are separate and distinct from Fox, and Fox does not have any employment nor consulting agreements with any treating physicians. As such, these physicians have no incentive to over or inappropriately prescribe therapy services.

Courts have found that “the Secretary is expected to place significant reliance on the informed opinion of a treating physician and apply ‘some extra weight’ to the opinion, or supply ‘a reasoned basis, in conformity with statutory purpose, for declining to do so.’” *Smith on Behalf of McDonald v. Shalala*, 855 F. Supp. 658, 664 (D. Vt. 1994) (internal citations omitted). See also *Bergeron v. Shalala*, 855 F. Supp. 665, 668 (D. Vt. 1994) (same); *State of N.Y. on Behalf of Holland v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991) (same). The *McDonald* court, which overturned the denial of the beneficiary's coverage, found that “[t]he [lower court's] interpretation of McDonald's condition is flawed because it impermissibly relies on ex post facto determinations. [Her treating physician's] opinion as to necessary care, rendered at the time of certification, should not have been rejected on the basis of a retrospective review of McDonald's vital signs.” *McDonald*, 855 F. Supp. at 663. Similarly, “[t]he opinion of a treating physician on the nature or severity of a claimant's impairments is binding if it is supported by medical evidence and not contradicted by substantial evidence in the record.” *Selian v. Astrue*, 708 F.3d 409, 418 (2d Cir. 2013).

Indeed, one court recently found that in Medicare cases, “caselaw requires [judges] to give some extra weight to a treating physician's opinion, or supply a reasoned basis for declining to do so.” *Executive Director of Office of Vermont Health Access ex rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 441, 450 (D. Vt. 2010) (emphasis added). In *Vermont Health Access*, the beneficiary's treating physician certified that the beneficiary needed skilled nursing services by executing plans of care, thus showing that the physician found the services were reasonable and necessary. The District Court found that the lower court had erred in not giving “extra weight” to the certifications, which were the treating physician's contemporaneous opinions. *Id.* The District Court ultimately held that a judge “cannot substitute his or her own judgment for that of a physician” or rely on an “ex post facto interpretation” of the medical record. *Id.* at 442. See also *Klementowski v. Secretary*, 801 F. Supp. 1022, 1026 (W.D.N.Y. 1992) (encouraging courts to apply the treating physician rule in Medicare cases).⁷

⁷ Similarly, courts in this Circuit have repeatedly applied the treating physician rule—which entitles a treating physician's opinion to controlling weight if it is well-supported by medically-acceptable techniques and is not inconsistent with other evidence in the record—to find that the patient's treating physician, who has examined the patient and is most familiar with the patient's condition, is in the best position to make medical necessity determinations. See *Hipensteel v. Social Security Administration*, 302 F. Supp. 2d 382 (M.D. Pa. 2001) (noting that “the ‘treating physician rule’ is widely accepted in the Third Circuit”); *Edgerton v. CNA Ins., Co.*, 215 F. Supp. 2d 541, 549 (E.D. Pa. 2002) (finding that treating physicians' opinions should be entitled to substantial weight because they are medical professionals most able to provide complete pictures of patients' medical conditions and bring unique perspectives that cannot be obtained from objective medical findings or individual medical reports). See also

In fact, the OIG itself has acknowledged that a patient's treating physician is in the best position to determine when services are medically necessary. See OIG, Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services (Jan. 1999) (finding that "in determining what services are medically necessary, Medicare primarily relies on the professional judgment of the beneficiary's treating physician, since he or she knows the patient's history and makes critical decisions, such as admitting the patient to the hospital; ordering tests, drugs, and treatments; and determining the length of treatment"); OIG, Ordering Medicare Equipment and Supplies: Physician-Patient Relationship, OEI-02-97-00080 (Feb. 1999) ("Medicare recognizes the physician as the key figure in determining the appropriate utilization of all medical services."). Even in the OIG's draft Fox audit report it acknowledged that "Medicare contractors shall determine the necessity of services based on the delivery of services as directed in the beneficiary's plan . . ." as certified by the beneficiary's treating physician.

The OIG failed to meet the requirement that it give extra weight to the treating physicians' determinations that these patients had the potential to benefit from therapy services. To the contrary, the OIG's determination that certain patients lacked the "expectation of significant improvement" is conclusory at best and provides no reasoned basis for declining to afford extra weight to the treating physicians' opinions on the need for and benefit of therapy.

Fox example, in the case of patient number 72, the OIG denied services on October 18, 2013, in part because it claimed that "[t]here was no reasonable expectation of significant improvement." This basis for denial is contrary to *Jimmo*, as well as the determinations of the clinician and the treating physician that the patient had the potential to benefit from therapy.

Patient number 72's treating physician certified the plan of care, which indicated that the patient's "Rehab Potential" was "excellent." According to the OIG, by October 18, 2013, the patient had attended multiple treatment sessions without significant improvement in ambulation distance or decreased burden of assistance over the previous six sessions. Contrary to the OIG's claim, as of October 18, the patient had gone from 2 feet in parallel bars to 20 feet outside of the stability of the parallel bars, and he moved to using a rolling walker. The OIG failed to recognize this substantial improvement in the patient's ambulation. Further, the OIG narrowly focused on ambulation distance, neglecting to mention the patient's gains in strength, balance, and transfers, which are clearly recorded in the Progress Reports. Finally, given the medical record evidence that fluctuating improvements in transfers were in fact made beyond the date of denied service, the OIG's conclusory ex post facto allegation that there was no expectation of improvement is insufficient to overcome the treating physician's determination that the patient's

Kertesz v. Crescent Hills Coal Co., 788 F.2d 158, 163 (3d Cir. 1986) ("In weighing medical evidence to evaluate the reasoning and credibility of a medical expert, however, the ALJ may not exercise 'absolute discretion to credit and discredit the experts' medical evidence.' 'By independently reviewing and interpreting the laboratory reports the ALJ impermissibly substitutes his own judgment for that of a physician; an ALJ is not free to set his own expertise against that of a physician who presents competent evidence.'") (internal citation omitted); *Fargnoli v. Massanari*, 247 F.3d 34, 43 (3d Cir. 2001) ("Under applicable regulations and the law of this Court, opinions of a claimant's treating physician are entitled to substantial and at times even controlling weight.").

potential to benefit from therapy was “excellent” and the actual improvement the patient made during the course of treatment.

For these reasons, as well as those set forth more fully in Exhibit 3 attached hereto, the OIG improperly denied coverage for patient number 72.

- 3) Even Assuming The OIG’s Allegation That Certain Patients Were Not Expected To Improve Or Only Obtained Minimal Gains Is Correct, Fox Provided Skilled Care That Was Necessary For A Safe And Effective Maintenance Program Or To Prevent Decline In Function.

As CMS recognizes, skilled therapy services that do not meet the criteria for rehabilitative therapy may be covered under a maintenance program. MBPM, Chapter 15, § 220.2(D). The purpose of a maintenance program is to maintain a patient’s functional status or to prevent or slow further deterioration in a patient’s function. *Id.*

Coverage for skilled therapy services related to the establishment of a reasonable and necessary maintenance program is available in the following circumstances: (a) to design a maintenance program to maintain the patient’s current condition or to prevent or slow further deterioration; (b) to instruct the patient or appropriate caregiver regarding the maintenance program; or (c) to periodically reevaluate or reassess the maintenance program. *Id.*

Once a maintenance program is established, skilled therapy services are covered when “an individualized assessment of the patient’s clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of safe and effective services in a maintenance program.” *Id.* This occurs when:

- (a) the therapy procedures required to maintain the patient’s current function or to prevent or slow further deterioration are of such complexity and sophistication that the skills of a qualified therapist are required to furnish the therapy procedure or
- (b) the particular patient’s special medical complications require the skills of a qualified therapist to furnish a therapy service required to maintain the patient’s current function or to prevent or slow further deterioration, even if the skills of a therapist are not ordinarily needed to perform such therapy procedures.

Id. For example, the skilled services of a therapist would be required to safely carry out a maintenance program given a particular patient’s special medical complications. A maintenance program would thus be covered if a patient had “an unhealed, unstable fracture that requires regular exercise to maintain function until the fracture heals, [necessitating] the skills of a therapist . . . to ensure that the fractured extremity is maintained in proper position and alignment during ranges of motion exercises.” *Id.*

Even if the OIG's allegation that certain patients could not be expected to improve is correct, Fox provided skilled care that was necessary to safely and effectively maintain the patients' conditions or prevent or slow decline in the patients' conditions. Thus, the services provided qualify for coverage as maintenance therapy. The OIG provided no explanation about why the services would not be covered under a maintenance program other than the bare conclusion in the spreadsheet that the care was not necessary for a maintenance program. The OIG consequently violated the Medicare regulations and an existing Court Order which require that reimbursement be provided for maintenance therapy.

For example, in the case of patient number 6, the OIG denied coverage because "[t]here was no expectation of significant improvement within a reasonable and predictable period of time, OR care was not necessary for a safe and effective maintenance program." The OIG indicated that the treatment "was maintenance in nature and not medically necessary." But, as required by *Jimmo*, maintenance therapy is covered under Medicare. The OIG never determined or alluded to the fact that the care was not skilled, and it did not apply the deficiency code regarding lack of skilled care to this case. The OIG also did not otherwise explain why the maintenance therapy would not qualify for coverage in this case. Rather, it made the conclusory finding that "[a]n independent home exercise program . . . would have better met the patient's needs." This case is an example of the OIG's failure to consider that, regardless of a patient's potential to improve, patients are entitled to covered maintenance therapy.

Similarly, in the case of patient number 61, the OIG denied coverage in part because "[t]here was no expectation of significant improvement within a reasonable and predictable period of time, OR care was not necessary for a safe and effective maintenance program." The OIG did not explain which of these two reasons applied in the case of this patient. Assuming the OIG claims that the first reason applies, it is illegal to deny coverage based on a lack of expected improvement. Assuming the OIG claims that the second reason applies, maintenance therapy is covered under Medicare. The OIG did not allege that the care was not skilled, and it did not apply the deficiency code regarding lack of skilled care to this case. The OIG also did not explain why maintenance therapy would not qualify for coverage in this case. Accordingly, this case is another example of the OIG's failure to recognize that maintenance therapy is covered by Medicare.

B. "SERVICES WERE NOT REASONABLE." THE OIG'S ALLEGATION THAT THE AMOUNT, FREQUENCY, AND DURATION OF SERVICES WERE NOT REASONABLE FOR 84 CLAIMS IS FLAWED.

In the OIG's spreadsheet, it alleged that the amount, frequency, and duration of services in 84 cases were not reasonable and consistent with standards of practice (without reference to alleged minimal gains). Fox addresses this allegation in the sections below to the extent that the OIG intends to rely on it as a basis for denial.

1) The OIG's Failure To Articulate The Specific Standard Of Practice That Was Allegedly Violated Or How It Was Allegedly Violated Prevents Fox From Properly Rebutting This Deficiency.

Although the OIG claimed that the amount, frequency, and duration of services were not consistent with "standards of practice," it failed to identify the specific standard of practice that was allegedly violated or how any such standard was violated in any case. CMS provides that acceptable practices for therapy services are found in Medicare manuals, Contractors' Local Coverage Determinations, and "guidelines and literature of the professions of physical therapy, occupational therapy and speech-language pathology." *See* MBPM, Chapter 15, § 220.2(B). Given CMS' endorsement of a multitude of sources for accepted practices, the OIG's failure to articulate a specific standard of practice that was allegedly violated is prejudicial to Fox's defense of the audit.

The OIG's failure becomes even more troubling after considering research conducted by the United States General Accounting Office, which revealed that national coverage standards leave key elements undefined, and Medicare carriers themselves differ in their interpretations of such standards. *See* United States General Accounting Office, "Medicare Part B Factors that Contribute to Variation in Denial Rates for Medical Necessity Across Six Carriers." Fox cannot be expected to know which of the many standards the OIG is alleging that Fox violated or how the OIG believes Fox violated the standard in each case and, consequently, Fox cannot provide a meaningful defense of its services.

Moreover, in many cases, OIG provided no explanation to support its denial; it simply stated in a conclusory fashion that "[t]he amount, frequency, and duration of the services provided were excessive." According to CMS, (1) "amount" means the number of times in a day the treatment will be provided; (2) "frequency" is the number of times in a week the treatment will be provided; and (3) "duration" means the number of weeks or the number of treatment sessions. MBPM, Chapter 15, § 220.1.2(B). It therefore appears that the OIG takes issue with the number of times in a day treatment was provided, the number of times per week treatment was provided, and the total number of treatment sessions as somehow violating some unknown standard of practice.

2) Although The OIG Does Not Cite Any Applicable Standard Of Practice, The Amount, Frequency, And Duration Of Services That Fox Provided Was Consistent With Standards Of Practice.

Fox complied with Novitas' utilization guidelines regarding the amount and frequency of physical and occupational therapy services, which provide for five timed physical therapy services and five timed occupational therapy services per patient per day, as well as 60 physical therapy services and 60 occupational therapy services per patient per month.

Fox also complied with the recommended frequency of services set forth in medical literature. For example, "[d]oing progressive resistance training 2-3 times a week can improve physical function in older adults, including reducing physical disability, some functional limitations (i.e. balance, gait speed, timed walk, timed 'up and go', chair rise, and climbing

stairs) and muscle weakness in older people.” CJ Liu and NK Latham, *Progressive Resistance Strength Training for Improving Physical Function in Older Adults*, COCHRANE DATABASE OF SYSTEMIC REVIEWS (Jul. 2009). Similarly, “[w]hen intensity to promote muscle strength (60% or more of 1RM) is used, recommended frequency is 2-3x/week, allowing 24-48 hours of rest in between sessions of the same muscle group.” Dale Avers PT, DPT, PhD & Marybeth Brown, PT, DPT, FAPTA, FACSM, *White Paper: Strength Training for the Older Adult*, JOURNAL OF GERIATRIC PHYSICAL THERAPY (2009). Fox rarely treats patients more than three times per week.

In most cases, Fox did not exceed the recommended duration of services set forth in medical literature: “[l]ong lasting and significant change in strength occurs over a 12 to 16 week period; however in most instances, aging adults are discharged from physical therapy in hospital and rehabilitation settings before such gains can be realized.” *Id.* The literature does not require that services cease after 16 weeks, so to the extent that Fox provided therapy beyond 16 weeks, the services are still entitled to be covered, as they were approved by the treating physician as necessary.

- 3) The Duration Of Services Were Reasonable And Consistent With Standards Of Practice Because The Treating Physicians Certified The Plans Of Care.

Despite the OIG’s failure to identify the specific standards of practice at issue, Fox properly relied on the treating physicians’ opinions that the duration of services were reasonable and medically necessary. The patients’ treating physicians certified the plans of care, which set forth the duration of services to be provided, thus establishing that the services provided in connection with the plan of care were reasonable and consistent with standards of practice. *See* MBPM, Chapter 15, § 220.1.2(B). A physician is required to certify that the patient “needs” outpatient therapy services by certifying the plan of care.⁸ *See* 42 CFR § 424.24; MBPM, Chapter 15, § 220.1. Moreover, in certain cases, the determination of medical necessity is further corroborated by the treating physician’s recertification of the plan of care. Thus, the physician’s certification is a determination by the treating physician of the medical necessity of the amount, frequency, and duration of services provided.

The proper inquiry is whether the physician determines that the patient “needs” the amount, frequency, and duration of services set forth in the plan of care, not whether the OIG thinks services were provided too frequently or for too long of a period of time. As CMS acknowledges, “[f]actors that contribute to need vary, but in general they relate to such factors as the patient’s diagnoses, complicating factors, age, severity, time since onset/acuity, self-efficacy/motivation, cognitive ability, prognosis, and/or medical, psychological and social stability.” *See* MBPM, Chapter 15, § 220.3(B). This is the reason for the treating physician—the person

⁸ *See also* 42 CFR § 424.10 (“The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.”).

most familiar with the patient’s circumstances—having the responsibility to certify that the treatment regimen in the plan of care is expected to address the patient’s “needs.”

Further, CMS directs treating physicians to certify a plan of care only until a date certain, restricting the duration of therapy beyond that date, if the physician believes that he needs to see the patient to determine whether more therapy is needed. *See* MBPM, Chapter 15, § 220.1.3(C). In all 85 cases at issue, the plans of care were certified for their entire durations. No treating physicians believed that there was any question regarding the appropriateness of the duration of the therapy services.

As an example of the arbitrary nature of the OIG’s conclusions, the auditors often alleged that therapy was “excessive” without regard to the date of the evaluation and plan of care, which was certified by the treating physician thus confirming that therapy was necessary. As the charts below indicate, on a number occasions, the OIG denied services less than 10 days after the patients’ plans of care.⁹ The physician-certified plans of care for these patients provided for therapy sessions over courses of between 60 and 90 days. Despite this, the OIG denied services as being “excessive” within 10 days of the dates of the plans of care. The OIG’s denials thus show that the OIG ignored the opinions of the patients’ treating physicians.

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 40	3/12/2014	3/19/2014	4/21/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 23	5/5/2014	5/12/2014	7/28/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 46	1/23/2014	1/31/2014	3/10/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 22	10/15/2014	10/23/2014	12/12/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 15	2/16/2015	2/23/2015	5/15/2015

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Re-certified Plan</i>	<i>Denied Service</i>	<i>Discharge</i>
Number 48	1/9/2014	3/6/2014	3/10/2014	5/11/2014

⁹ The following charts are a sample of occasions on which the OIG denied services less than 10 days after the patients’ certified plans of care.

In other cases, the OIG denied services as allegedly “excessive” less than 10 days before the date of a re-certified plan of care. In re-certifying the plans of care, the treating physicians determined that these patients needed additional therapy. The certification of plans of care for additional therapy after the date on which the OIG denied services undermines the OIG’s finding that these patients received excessive services.

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Re-certified Plan</i>	<i>Discharge</i>
Number 14	11/26/2013	1/20/2014	1/24/2014	3/21/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Re-certified Plan</i>	<i>Discharge</i>
Number 56	4/1/2014	5/27/2014	6/2/2014	6/25/2014

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Denied Service</i>	<i>Re-certified Plan</i>	<i>Discharge</i>
Number 93	11/29/2014	2/25/2015	2/25/2015	4/22/2015

<i>Patient</i>	<i>Evaluation and Plan of Care</i>	<i>Re-certified Plan</i>	<i>Denied Service</i>	<i>Re-certified Plan</i>	<i>Discharge</i>
Number 30	2/19/2015	5/19/2015	6/11/2015	6/18/2015	8/17/2015

In sum, these charts reflect only a sample of the cases which show that there is a direct contradiction between the date upon which the OIG determined services were not necessary and the treating physicians’ determinations that services were necessary in their certifications of the plans of care. The OIG thus failed to fulfill the legal requirement that it give the proper weight to the opinions of the beneficiaries’ treating physicians, or otherwise provide a reasoned basis to reject the treating physicians’ judgments.

Further, the auditors arbitrarily alleged that therapy was “excessive” without regard to the number of therapy sessions the patient had completed at the time of the denied services. The following are examples of instances in which the OIG claimed that the services were excessive when a patient had only five or fewer therapy sessions with a Fox clinician, despite the fact that the certified plans of care for these patients provided for many more than five sessions.

- In the case of patient number 45, the OIG alleged that “[t]he amount, frequency, and duration of the services provided were excessive” on the beneficiary’s *second* therapy session. The plan of care, however, provided for approximately 24 therapy sessions.
- The OIG claimed that “[t]he number of treatments was excessive” on patient number 15’s *third* therapy session. The certified plan of care for the patient provided for approximately 36 therapy sessions. In the cases of patient numbers

23 and 78, the OIG claimed that “[t]he amount, frequency, and duration of the services provided were excessive” on only the *third* therapy sessions. The certified plans of care for these patients provided for approximately 24 therapy sessions each.

- On only the *fourth* therapy sessions in the cases of patient numbers 22 and 40, the OIG claimed that “[t]he number of treatments was excessive.” The certified plan of care for patient number 22 provided for approximately 20 therapy sessions; and the certified plan for patient number 40 provided for approximately 36 therapy sessions. Similarly, in the case of patient number 86, the OIG claimed that “[t]he amount, frequency, and duration of the services provided were excessive” on the beneficiary’s *fourth* therapy session, despite the fact that the certified plan of care provided for approximately 24 therapy sessions.
- The OIG claimed that “[t]he number of treatments was excessive” in the case of patient number 71 on only her *fourth and fifth* therapy sessions, despite the fact that the certified plan of care for the patient provided for approximately 36 therapy sessions.
- In the case of patient number 19, the OIG alleged that the “[t]he number of treatments was excessive” on only her *fifth* therapy session. The certified plan of care for the patient provided for 24 approximately therapy sessions. Similarly, in the case of patient number 80, the OIG claimed that “[t]he amount, frequency, and duration of the services provided were excessive” on the beneficiary’s *fifth* therapy session, despite the fact that the certified plan of care provided for approximately 24 therapy sessions.

The OIG also alleged that therapy was excessive without regard to the total length of the course of care. The following are examples of instances when the OIG claimed that the services were excessive when a patient had a total of eight or fewer visits, despite the fact that the certified plans of care for these patients provided for many more sessions. Further, the following cases highlight that Fox clinicians understand and follow their obligation to discharge patients when skilled care is no longer needed.

- In the case of patient number 61, the OIG alleged that “[t]he amount, frequency, and duration of the services provided were excessive” when the patient’s entire course of care was only five visits. Her certified plan of care provided for approximately 16 therapy sessions.
- Regarding patient number 46, the OIG claimed that “[t]he number of treatments was excessive” when the entire course of care for the patient was a total of only six therapy sessions. The certified plan of care for the patient provided for approximately 24 therapy sessions.
- Regarding patient number 34, the OIG claimed that “[t]he amount, frequency, and duration of the services provided were excessive,” but the patient’s entire course

of care was only seven visits. Her certified plan of care provided for approximately 24 therapy sessions.

- In patient number 83's case, the OIG claimed that "[t]he number of visits was excessive" when the entire course of care for the patient was a total of only eight therapy sessions. The certified plan of care for the patient provided for approximately 16 therapy sessions.

In sum, the OIG's conclusion that the amount, frequency, and duration of services were not reasonable and consistent with standards of practice is not only contrary to the determinations of the beneficiaries' treating physicians and inconsistent with the standards of practice, but is arbitrary on its face. Accordingly, the OIG failed to meet the requirement, as fully set forth above, that it give extra weight to the treating physicians' determinations, or otherwise provide a reasoned basis to reject the treating physicians' judgments that the amount, frequency, and duration of therapy services was appropriate given the patients' needs.

- 4) A Review Of The Record In Its Entirety Shows That The Amount, Frequency, And Duration Of Services Were Reasonable And Consistent With Standards Of Practice.

In 84 cases, the OIG found that Fox provided services in an amount, frequency, and duration that was not reasonable and consistent with standards of practice. Regardless of the OIG's failure to identify the specific standard of practice that the OIG claims was violated, Fox maintains that all services were skilled and provided in accordance with all physical, occupational, and speech therapy standards of practice.

CMS has advised that "the frequency or duration of the treatment may not be used alone to determine medical necessity, but they should be considered with other factors such as condition, progress, and treatment type to provide the most effective and efficient means to achieve the patients' goals." MBPM, Chapter 15, § 220.1.2(B). CMS acknowledges that "complexities" are complicating factors that may influence the frequency and/or duration of treatment. *Id.* at § 220(A). Complexities include "patient factors such as age, severity, acuity, multiple conditions, and motivation, or by the patient's social circumstances such as the support of a significant other or the availability of transportation to therapy." *Id.* Similarly, in providing guidance on evaluating whether changes to the amount, frequency, or duration should be made, CMS advises that a clinician should consider any comorbidities and the abilities of the patient. *Id.* at § 220.1.2(B). In other words, patients with different physical needs respond to treatment at different levels and times. The amount, frequency, and duration of treatment "depend[s] on the individuals' needs." *Id.*

It is clear that the OIG improperly failed to consider the patient's medical record *in toto* when it determined that the amount, frequency, and duration of services was not reasonable and consistent with standards of practice. A review of the record requires more than a mechanical evaluation of the services provided under each claim. CMS specifically directs contractors to "consider the entire record when reviewing claims for medical necessity . . ." MBPM, Chapter 15, § 220.3(A). Accordingly, it is appropriate to consider the specific condition(s) of the patient

when determining whether services are medically necessary. *See id.* at § 220.2(B). The requirement that therapy services be “reasonable and necessary for the diagnosis or treatment of illness or injury” has been applied in connection with a beneficiary’s unique condition and individual needs. *See id.*¹⁰

For example, the OIG failed to consider patient number 64’s specific condition in alleging that the amount, frequency, and duration of services were excessive on only the *sixth* visit. The patient had recently suffered two falls resulting in pelvic fractures, thus necessitating skilled care beyond the mere six episodes the OIG approved. Studies show that “[t]he management of elderly and octogenarian patients with pelvis fractures is fraught with increased mortality relative to their adult counterparts.” Matityahu, Elson, Morshed and Marmor, *Survivorship and Severe Complications Are Worse for Octogenarians and Elderly Patients with Pelvis Fractures as Compared to Adults: Data from the National Trauma Data Bank*, JOURNAL OF OSTEOPOROSIS (2012). The patient also had a history of chronic obstructive pulmonary disease, heart attack, high blood pressure, and depression. Prematurely discharging the patient would have raised a safety issue since the patient required assistance for loss of balance with mobility tasks and exercises.

In sum, and considering the more detailed analysis set forth in Exhibit 4, the OIG improperly denied services to patient number 64.

- C. *“SERVICES WERE NOT SPECIFIC OR EFFECTIVE.” THE OIG IMPROPERLY CLAIMED THAT 26 SERVICES WERE NOT SPECIFIC AND/OR AN EFFECTIVE TREATMENT FOR THE PATIENT’S CONDITION.*
- 1) The OIG Violated The “Improvement Standard” In Its Implementation Of The Requirement That Services Be Specific And Effective.

The OIG alleged that services were not specific or effective for 26 claims and highlighted the case of patient number 24 as an example. In the OIG’s discussion of the patient, the OIG alleged that “[t]he medical records did not show functional improvements after the occupational therapy. . . .” This claim that the patient did not show “functional improvement” violates the “Improvement Standard” because it is merely another way of stating that improvement is a requirement for coverage. Thus, the OIG is improperly interpreting the requirement that services be specific and effective. CMS merely requires that “services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient’s condition,” and CMS provides examples of sources for such acceptable practices. MBPM, Chapter 15, § 220.2(B). CMS does not require that the services result in “functional improvement.” *See id.* And, in fact, as explained above, CMS explicitly recognizes that improvement is an improper basis upon which to deny coverage.

¹⁰ *See also* 42 CFR §§ 409.32-409.33 (in the context of post-hospital skilled nursing care, determination of “reasonable and necessary” must consider individual condition and needs of each patient).

The OIG's improper implementation of the "Improvement Standard" occurred in nearly half of the 26 cases for which it denied coverage based on its allegation that services were not specific or effective. By way of example only, the OIG referenced improvement in some of the 26 cases as follows:

- Patient number 34: "However, as of 2/2/2015, there had been no significant improvement."
 - Patient number 46: "The distance and level of assistance required had not changed since the second treatment."
 - Patient number 48: "However, as of 3/10/2014, the patient was attending the 12th treatment and the impairments identified at the initial evaluation had not improved significantly."
 - Patient number 78: "Her condition had not changed."
 - Patient number 98: "She continued to require moderate assistance for transfers and her burden of care had not decreased."
- 2) Services Were Specific And Effective Treatments For The Patients' Conditions Because The Treating Physicians Certified The Plans Of Care.

The patients' treating physicians certified the plans of care, which set forth the types of services to be provided, thus establishing that the services were specific and/or an effective treatment for the patients' conditions in the 26 cases at issue. A physician is required to certify that the patient "needs" outpatient therapy services by certifying the plan of care. *See* 42 CFR § 424.24; MBPM, Chapter 15, § 220.1. Moreover, in some cases, the determination of medical necessity is further corroborated by the treating physician's recertification of the plan of care. Thus, the physician's certification is a determination by the treating physician that the services provided would be specific and effective for the patient's condition. Accordingly, the OIG's conclusion that the services were not specific and/or an effective treatment for the patients' conditions ignores the determinations of the patients' needs as certified by the treating physicians, and the OIG cited no basis on which to over-rule the treating physicians' opinions.

The proper inquiry is whether the physician determines that the patient "needs" the type of services set forth in the plan of care. As CMS acknowledges, "[f]actors that contribute to need vary, but in general they relate to such factors as the patient's diagnoses, complicating factors, age, severity, time since onset/acuity, self-efficacy/motivation, cognitive ability, prognosis, and/or medical, psychological and social stability." *See* MBPM, Chapter 15, § 220.3(B). This is the reason for the treating physician—the professional most familiar with the patient's circumstances—having the responsibility to certify that the types of services in the plan of care are specific and effective to address the patient's "needs."

For the reasons set forth above, the OIG was required to give extra weight to the treating physicians' determinations that the services were specific and effective treatments. The OIG, however, failed to do so and did not otherwise explain why deference to the treating physicians' opinions was not warranted. The OIG thus improperly denied coverage.

3) A Review Of The Medical Records In Their Entirety Shows That The Services Were In Fact Specific And Effective Treatments For The Patients' Conditions.

The OIG improperly failed to consider the patients' medical records *in toto* when it determined that the services were not specific and/or an effective treatment for the patients' conditions. A review of the record requires more than a mechanical evaluation of the services provided under each claim. CMS specifically directs contractors to "consider the entire record when reviewing claims for medical necessity so that the absence of an individual item of documentation does not negate the medical necessity of a service when the documentation as a whole indicates the service is necessary." MBPM, Chapter 15, § 220.3(A). Accordingly, it is appropriate to consider the specific condition(s) of the patient when determining whether services are medically necessary. *See id.* at § 220.2(B). The requirement that therapy services be "reasonable and necessary for the diagnosis or treatment of illness or injury" has been applied in connection with a beneficiary's unique condition and individual needs. *Id.*¹¹

In the OIG's draft report, it referenced the treatment provided to patient number 24 as an example of services that were not specific to or effective for the beneficiary's condition. A review of the patient files provided to the OIG, however, shows that the care was both specific to and effective for the patient's condition. On February 5, 2015, the date in question, services specifically addressed the deficits noted on the patient's evaluation. The services addressed the patient's noted decline in performing activities of daily living, as the clinician guided the patient by both verbal instruction and visual demonstration in grooming. The services also addressed her noted decrease in strength because the clinician did four strength exercises with the patient, giving minimum to moderate assistance and visual and tactile cues to ensure the exercises were performed properly. Finally, to address the patient's noted decrease in balance, the clinician did a balance activity with the patient, which required moderate assistance and cues.

The services were not only specific, they were also effective. At discharge, the patient required significantly less assistance with her activities of daily living, and the staff reported that the patient was not refusing activities of daily living as frequently. Specifically, the patient went from maximum assistance with bathing, dressing, and grooming to minimum assistance with bathing and dressing, and moderate assistance with grooming. Further, the patient's transfers improved from minimal assistance to independent. Finally, the patient reported less pain at the time of discharge.

¹¹ *See also* 42 CFR §§ 409.32-409.33 (in the context of post-hospital skilled nursing care, the determination of "reasonable and necessary" must consider the individual condition and needs of each patient).

Given this, as well as the more detailed analysis set forth in Exhibit 5, the OIG improperly denied services to patient number 24.

D. *"SERVICES DID NOT REQUIRE THE SKILLS OF A THERAPIST." THE OIG INCORRECTLY FOUND THAT SERVICES DID NOT REQUIRE THE SKILL OF A LICENSED THERAPIST IN FIVE CASES.*

- 1) The OIG Improperly Failed To Consider The Unique Conditions Of Fox's Patients, The Safety Concerns At Issue, And The Entitlement To Maintenance Therapy In Finding The Care Was Unskilled.

In 5 cases, the OIG determined that the care provided was unskilled. Contrary to the OIG's conclusions, skilled care was provided in these five cases. In fact, in accordance with the skilled rehabilitative therapy services that CMS recognizes, all 85 cases included the following: (1) performance of evaluations; (2) establishment of treatment goals specific to the patients' disabilities and designed to address problems identified in the evaluations; (3) development of plans of care addressing the patients' disorders, including establishing procedures to obtain goals and determining the frequency and intensity of treatment; and (4) continued assessment and analysis at regular intervals. *See* MBPM, Chapter 15, § 220.2(C).

As CMS has explained, "a therapist's skills may be documented, for example, by the clinician's descriptions of their skilled treatment, the changes made to the treatment due to a clinician's assessment of the patient's needs on a particular treatment day or changes due to progress the clinician judged sufficient to modify the treatment toward the next more complex or difficult task." *See id.* at § 220.3(B). Critically, the fact that a non-skilled caregiver may provide services to a patient, such as assisting him with bathing or dressing, does not compel a finding that the patient did not require the skilled services of a therapist as well. *See Executive Director of Office of Vermont Health Access ex rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 455 (D. Vt. 2010).¹²

Moreover, clinicians are not required to provide descriptions of skilled interventions in their treatment notes. *See* MBPM, Chapter 15, § 220.3(E). Descriptions of skilled interventions should instead be included in the plan or progress report. *Id.* In all five cases, the Fox clinicians documented the skilled nature of the services provided in the plans or progress reports, thus complying with CMS' requirements for documenting skilled care. For instance, in the case of patient number 71, a case in which the OIG denied services due to an alleged lack of skilled care, the progress report dated October 21, 2014 shows that the clinician provided skilled care. By way of example only, the clinician worked with the patient on ambulation by providing minimum physical assistance, tactile facilitation, and verbal instruction for a number of gait deviations listed, which an unskilled caregiver would not be able to perform.

¹² In the skilled nursing context, "the fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse." 42 CFR § 409.44(b)(1)(iii).

Finally, in several cases, the OIG claimed that services were not covered because “[t]here was no new injury or impairing condition.” There is no requirement that a new injury or impairing condition occur in order for care to be skilled, and the OIG never alleges otherwise. In fact, courts have found that “[a]n elderly claimant need not risk a deterioration of his fragile health to validate the continuing requirement for skilled care.” *Executive Director of Office of Vermont Health Access ex rel. Carey*, 698 F. Supp. 2d at 454 (internal quotations omitted). Similarly, “it would be ‘illogical’ to hold that, because a claimant did not experience the complications sought to be avoided by the services provided, those services were not reasonable and necessary.” *Id.* (internal citation omitted). Thus, in considering the specific needs of geriatric patients, treatment which has stabilized a patient’s health does not render continued care unskilled. *Id.*

i. *In Light Of The Ages And Medical Conditions Of Fox’s Patients, Fox’s Clinicians Were Providing Skilled Care.*

A patient’s age and condition must be considered in determining whether services are skilled. CMS acknowledges that “. . . a beneficiary’s particular medical condition is a valid factor in deciding if skilled therapy services are needed . . .” MBPM, Chapter 15, § 220.2(B).

Likewise, in the home health context, “[a] service that is ordinarily considered unskilled could be considered a skilled therapy service in cases where there is clear documentation that, because of special medical complications, skilled rehabilitation personnel are required to perform the service.” MBPM, Chapter 7, § 40.2.1. In analyzing the need for skilled care, all of the patient’s conditions and the aggregate of services provided must be considered as a whole, rather than merely reviewing the specific services provided. *Smith on Behalf of McDonald v. Shalala*, 855 F. Supp. 658, 662, 664 (D. Vt. 1994) (internal citations omitted).¹³

In concluding that care was not skilled, the OIG ignored CMS’s guidance to consider the ages and medical conditions of Fox’s patients. *See* MBPM, Chapter 15, § 220.2(B). For

¹³ Similar guidance is provided in the regulations applicable to post-hospital skilled nursing care:

[a] condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled . . . may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the skilled services they require, must be documented by physicians’ orders and nursing or therapy notes.

42 CFR § 409.32(b). *See also* 42 CFR § 409.33(a)(1)(ii) (providing that “the management of the plan of care would require the skills of a nurse even though the individual services are not skilled” when “the nature of the patient’s condition, age, and immobility create a high potential for serious complications”); *Executive Director of Office of Vermont Health Access ex rel. Carey*, 698 F. Supp. 2d at 456 (“If the patient’s overall condition, including his or her age and immobility, supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, ‘it is appropriate to infer that skilled services are being provided.’”) (internal citations omitted).

example, in the case of patient number 71, the OIG improperly found that care was not skilled on only her fourth and fifth treatment sessions because it failed to consider her medical conditions. Before being treated by Fox, the patient had experienced a thoracic fracture and underwent two kyphoplasties. She also had a history of atrial fibrillation, multiple sclerosis, and osteoporosis. Based on these complexities alone, her care required the skill of a clinician to restore her function and strength.

Moreover, skilled care was documented on the dates of service in question, September 3, 2014 and September 4, 2014. The clinician worked on transfers with the patient, giving the patient assistance, tactile facilitation, and verbal instruction for balance, safety, posture, and technique. Additionally, the clinician assisted the patient in her performance of 13 lower extremity and trunk exercises and several balance exercises; all but one exercise required assistance and cues by the clinician for proper technique and/or posture. Proper posture and technique is crucial during mobility and therapeutic exercises, especially for this patient, who had severe osteoporosis, prior vertebral fractures, and multiple sclerosis. The therapy program could not have been safely transferred to an unskilled worker who was untrained in these disease processes and inexperienced in the proper and safe execution of exercises and mobility.

Thus, for these reasons and those set forth more fully in Exhibit 6 attached hereto, the OIG's denial of coverage for patient number 71 was improper.

The OIG also ignored CMS' guidance to consider the ages and medical conditions of Fox's patients when it found that care was not covered because the patients could have treated themselves as part of a home exercise plan in 64 of the 85 cases (75% of the denied cases). This finding fails to consider that the beneficiaries have no medical training background, and their ages and complex medical conditions likely prevent them from effectively self-managing their conditions. Expecting Fox patients to immediately understand and properly perform home programs is thus impractical in many cases. Fox's therapists have years of education and training, and the skilled hands-on work they perform—which includes monitoring geriatric patients with multiple co-morbidities while they engage in exercises—is not always capable of being translated into an effective home program. Indeed, in two cases, patient number 91 and patient number 95, the OIG denied services on only the *second* visit, claiming that a home exercise program would have been sufficient. Such a finding unrealistically expects that the clinicians would be able to properly evaluate and train a medically complex geriatric patient on a home exercise program in only one visit.

ii. *Fox's Clinicians Were Providing Skilled Care Because Fox's Patients Present Unique Safety Concerns.*

Patient safety must also be considered in determining whether services are skilled. According to CMS, skilled care “shall be of such a level of complexity and sophistication or the condition of the patient shall be such that *the services required can be safely and effectively performed only by a therapist.*” MBPM, Chapter 15, § 220.2(B) (emphasis added). For example:

[w]here there is an unhealed, unstable fracture that requires regular exercise to maintain function until the fracture heals, the skills of a therapist may be needed to ensure that the fractured extremity is maintained in proper position and alignment during range of motion exercises. In this case, since the skills of a therapist may be required to *safely carry out the maintenance program* given this particular patient's special medical complications, therapy services would be covered.

Id. at § 220.2(D) (emphasis added).

Similarly, the Regulations explain that services may qualify as skilled rehabilitation services due to safety concerns: “[t]he development, management, and evaluation of a patient care plan based on the physician’s orders constitute skilled services when, because of the patient’s physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient’s needs, promote recovery, and *ensure medical safety.*” 42 CFR § 409.33(a)(1)(i) (emphasis added). The Regulations likewise provide that therapeutic exercises or activities are covered as skilled therapy when, “because of the type of exercises employed or the condition of the patient, [they] must be performed by or under the supervision of a qualified physical therapist or occupational therapist *to ensure the safety of the patient* and the effectiveness of the treatment.” 42 CFR § 409.33(c)(2) (emphasis added).

Safety concerns are especially present in Fox’s patient population, which consists of geriatric patients suffering from multiple co-morbidities. Thus, it is more likely that safety concerns would necessitate skilled care in Fox’s patient population. The OIG improperly failed to take these safety concerns into consideration when concluding that care was unskilled.

For example, the OIG denied services provided to patient number 23 on only her third treatment session, despite her requiring skilled care due to the safety concern she presented. The patient presented a safety concern because her oxygen saturation levels dipped during therapy. On May 5, 2014, for instance, the patient’s oxygen saturation fell to 88%. Oxygen saturation levels that dip too low may result in a medical emergency. The clinician closely monitored the patient during therapy in light of this safety concern.

Further, skilled care is clearly demonstrated on May 12, 2014, the date in question. Before and during exercise, the clinician monitored the patient’s vitals, including her heart rate, target heart rate estimation, blood pressure, and oxygen saturation. An unskilled caregiver could not perform this monitoring, which was necessitated by the safety concern that the patient presented. Thus, OIG incorrectly alleged that the patient’s services did not require the performance or supervision of a therapist and could have been provided using a home exercise program.

In sum, and for the reasons set forth more fully in Exhibit 7 attached hereto, the OIG improperly denied coverage to patient number 23.

iii. *Fox's Patients Are Entitled To Receive Skilled Maintenance Therapy.*

Therapists sometimes provide skilled services in the context of maintenance programs. Services related to establishing a reasonable and necessary maintenance program are considered skilled and, therefore, are covered in the following circumstances: (1) if the specialized skill, knowledge, and judgment of a qualified therapist are required to design a maintenance program to maintain the patient's current condition or to prevent or slow further deterioration; (2) if skilled therapy services by a qualified therapist are needed to instruct the patient or appropriate caregiver regarding the maintenance program; or (3) if skilled therapy services are needed for periodic reevaluations or reassessments of the maintenance program. MBPM, Chapter 15, § 220.2(D). *See also* 42 CFR § 409.33(c)(5).

Once the maintenance program is established, services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a qualified therapist are necessary for the performance of safe and effective services in a maintenance program. *Id.* This occurs when: (1) the therapy procedures are of such complexity and sophistication that the skills of a qualified therapist are required; or (2) the patient's special medical complications require the skills of a therapist, even if the skills of a therapist are not ordinarily needed to perform such therapy procedures. *Id.*¹⁴

As explained above, the OIG provided no explanation about why denied services would not be covered under a maintenance program other than the bare conclusion that the care was not necessary for a maintenance program. The OIG thus improperly failed to consider that Fox's patients are entitled to skilled maintenance therapy even if the OIG determined that the therapy was not rehabilitative.

¹⁴ Similar coverage is provided in the home health context:

[t]he unique clinical condition of a patient may require the specialized skills of a qualified therapist to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the complexity of the therapy services required to maintain function involve the use of complex and sophisticated therapy procedures to be delivered by the therapist himself/herself (and not an assistant) or the clinical condition of the patient is such that the complexity of the therapy services required to maintain function must be delivered by the therapist himself/herself (and not an assistant) in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services shall be covered.

42 CFR § 409.44(c)(2)(iii)(C).

2) The Care Was Skilled Because The Patients' Treating Physicians Found That The Patients' Conditions And Safety Concerns Warranted Skilled Care.

In certifying the plans of care, the patients' treating physicians determined that the care to be provided was skilled. A patient's treating physician is in the best position to determine that the services qualify as skilled due to the patient's age, condition, and medical complications, as well as the safety concerns at issue. The OIG failed to meet the requirement, as fully set forth above, that it give extra weight to the treating physicians' determinations that the care was skilled. To the contrary, the OIG's determination that the care provided was unskilled is conclusory and lacking in specific factual support.

In the OIG's draft report, it referenced the care provided to patient number 28 as an example of services that were not skilled. The care provided to the patient was in fact skilled because the clinician carefully progressed the patient's exercise and balance program by increasing reps, weights, theraband, and adding passive range of motion. CMS has found that adding new exercises or making changes to the exercise program demonstrates that services are skilled. See MBPM, Chapter 15, § 220.3(E). Additionally, the clinician cued the patient during transfer and gait training to address technique and gait deviations. Cuing to correct improper mobility patterns requires the skill of a clinician.

On the date of service in question, July 1, 2014, the clinician documented the following skilled care. The clinician provided "moderate tactile facilitation and verbal instruction" for safety and hand placement. During gait training, the clinician gave physical assistance and verbal instruction to the patient to increase her step length and speed. All six lower body strength exercises required verbal cues and demonstration for technique. Thus, the patient required the skill of a clinician to analyze and correct her mobility patterns for her exercises and ambulation.

For these reasons, and for the reasons set forth in more detail in Exhibit 8 attached hereto, the OIG improperly denied coverage for patient number 28.

E. "CARE WAS NOT APPROPRIATE." THE OIG'S CLAIM THAT CARE WAS NOT APPROPRIATE IN 85 CASES BECAUSE IT WAS NOT WITHIN THE STANDARDS OF PRACTICE GIVEN THE PATIENT'S DIAGNOSES, COMPLEXITIES, SEVERITIES, AND INTERACTION OF CURRENT ACTIVE CONDITION(S) IS FLAWED.

In the OIG's draft report, it alleged that the care in 85 cases was inappropriate based upon noncompliance with an unidentified standard of practice given the patient's diagnoses, complexities, severities, and interaction of current active conditions. In the OIG's spreadsheet, it simply claimed that the care in 85 cases was not appropriate given the patient's diagnoses, complexities, severities, and interaction of current active conditions (without alleging that any standards of practice were violated).

1) The OIG's Failure To Articulate The Specific Standard Of Practice That Was Allegedly Violated Or How It Was Allegedly Violated Prevents Fox From Properly Rebutting This Deficiency.

Although the OIG claimed that the beneficiaries received services that were not within standards of practice, it failed to identify the specific standard of practice that was allegedly violated or how any such standard was violated in any case. CMS provides that acceptable practices for therapy services are found in Medicare manuals, Contractors' Local Coverage Determinations, and "guidelines and literature of the professions of physical therapy, occupational therapy and speech-language pathology." *See* MBPM, Chapter 15, § 220.2(B). Given CMS' endorsement of a multitude of sources for accepted practices, the OIG's failure to articulate a specific standard of practice that was allegedly violated is prejudicial to Fox's defense of the audit.¹⁵

Fox cannot be expected to know which of the many standards the OIG is alleging Fox violated or how the OIG believes Fox violated the standard in each case and, consequently, Fox cannot provide a meaningful defense of its services. *See infra* at III(B)(1).

2) The Care That Fox Provided Was Appropriate Because The Patients' Treating Physicians Certified The Plans Of Care.

In all 85 cases, the OIG claimed that the care provided was not appropriate given the patient's diagnoses, complexities, severities, and interaction of current active conditions. By making such a conclusion, the OIG improperly usurped the judgment of the patients' treating physicians.

In certifying the plan of care, which sets forth the frequency, duration, and type of care to be provided, the patient's treating physician determined that the care would be appropriate for the patient. The patient's treating physician is in the best position to determine the appropriate care in light of the patient's diagnoses, complexities, severities, and interaction of current active conditions. The OIG failed to meet the requirement, as fully set forth above, that it give extra weight to the treating physician's determination that the care was appropriate. The auditors' conclusions do not provide a specific factual basis to undermine the treating physicians' judgments, and the auditors' findings are merely conclusory. Consequently, the OIG's conclusions violate the legal requirement that it provide deference to the treating physician's conclusions.

¹⁵ The OIG's failure becomes even more troubling after considering research conducted by the United States General Accounting Office, which revealed that national coverage standards leave key elements undefined, and Medicare carriers themselves differ in their interpretations of such standards. *See* United States General Accounting Office, "Medicare Part B Factors that Contribute to Variation in Denial Rates for Medical Necessity Across Six Carriers."

3) Given The Patients' Diagnoses, Complexities, Severities, And Interactions Of Conditions, The Care Was Appropriate.

Contrary to the OIG's claims, care was appropriate in all 85 cases given the patients' diagnoses, complexities, severities, and interactions of current active conditions. The appropriateness of the care provided in all 85 cases is more fully explained in the attached Appendices A and B.

In the OIG's draft report, it referenced the care provided to patient number 1 as an example of care that was not appropriate given the beneficiary's diagnoses, complexities, severities, and interaction of current active conditions. The patient had diagnoses of dementia and arthritis, as well as balance and mobility impairments. The care was appropriate because it addressed these issues through transfer and gait training, as well as strength and balance exercises. Further, studies show that "... exercise is important for the health of people with dementia." *Dementia: A NICE-SCIE Guidelines on Supporting People with Dementia* (2007). On the date in question, April 23, 2015, care included transfer and gait training that required verbal instruction and visual demonstration; six strength exercises which required minimum to moderate assistance, cues, and demonstration; and four therapeutic activities geared towards balance that required moderate to maximum assistance. The treatment on April 23 was thus appropriate given the strength, balance, transfer, and ambulation impairments found at evaluation.

In sum, and for the more detailed reasons set forth in Exhibit 9 attached hereto, the OIG improperly denied coverage to patient number 1 and should revise its draft findings accordingly.

*F. OTHER PROVISIONS OF THE SOCIAL SECURITY ACT AND MEDICARE MANUAL
LIMIT FOX'S LIABILITY WITH RESPECT TO ALL 85 DENIED CLAIMS.*

Fox is not liable for any alleged overpayments based on the five deficiencies that the OIG articulated, which all relate to a supposed lack of medical necessity, because Section 1879 of the Social Security Act limits Fox's liability.

Fox is not responsible for any of the 85 alleged overpayments because the OIG failed to consider that Section 1879 limits Fox's liability. In alleging that 85 claims should not have been reimbursed by Medicare, the OIG assigned each claim one or more of five deficiency codes. The OIG related all five deficiency codes to an alleged lack of medical necessity.

If a service is denied based on a finding that it was not reasonable and necessary, Section 1879 provides that liability for the non-covered service may be limited if the provider or practitioner did not know, and could not have been reasonably expected to know, that the service would not be covered. *See* 42 U.S.C. § 1395pp. In determining whether a provider or practitioner did not know or could not have been expected to know that a service would not be covered, the following are examples of things to be considered: prior notice that such services or comparable services were not covered; notice or constructive notice based on manual instructions, bulletins, written guides and directives, to the medical community of Medicare payment denial of such services; provision of services inconsistent with acceptable standards of

practice in the local medical community; and a utilization review committee having advised that the services were not covered. *See* 42 CFR § 411.406.

In believing that the services were medically necessary and otherwise appropriate, Fox provided services consistent with acceptable standards of practice in the local medical community. Fox properly relied on the treating physicians' certifications of the patients' plans of care, and it provided services in accordance with the certified plans. Thus, Fox did not know and could not have reasonably known that the services were not medically necessary.

Fox did not have prior notice, actual or constructive, that its services would be denied. The services at issue were denied as not being medically necessary after applying general principles of payment coverage to the particular services that Fox found were reasonable and necessary after analyzing each patient's specific medical conditions and history. Given the individualized determination that care was necessary in each case, Fox did not know and could not have been reasonably expected to know that the patient-tailored services would be denied based on prior denials or general guidance found in manuals, bulletins, or other broad policy statements. Additionally, no utilization review committee advised Fox that the services at issue would be denied. Section 1879 of the Social Security Act accordingly limits Fox's liability for the 85 alleged overpayments related to a lack of medical necessity.

Further, Fox satisfies the "without fault" provision contained in the Medicare Financial Management Manual. Fox exercised reasonable care in billing for and accepting payment because "it made full disclosure of all material facts . . . on the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations . . ." Medicare Financial Management Manual, Chapter 3, § 90. Thus, Fox "had a reasonable basis for assuming that the payment was correct." *Id.*

G. *"DOCUMENTATION DID NOT MEET MEDICARE REQUIREMENTS." THE OIG REFERENCED AN OUTDATED AND INCORRECT LEGAL STANDARD IN ITS ARGUMENT.*

The OIG denied one claim based on an outdated and incorrect legal requirement. According to the OIG: "[t]he minimum progress report period shall be at least once every 10 treatment days or at least once during each 30 calendar days, whichever is less. If the clinician has not written a progress report before the end of the progress report period, it shall be written within 7 calendar days after the end of the reporting period." This is not the correct requirement for progress reporting frequency, and it was not the requirement at the time of the audit period, which the OIG defined as July 1, 2013 to June 30, 2015.

The current requirement for progress reporting frequency is that "[t]he minimum progress report period shall be at least once every 10 treatment days. . . . If the clinician has not written a progress report before the end of the progress reporting period, it shall be written within 7 calendar days after the end of the reporting period." *See* MBPM, Chapter 15, § 220.3(D). This requirement was implemented on January 7, 2013 and was thus in effect at the time of the audited services. *See* CMS Manual System, Pub 100-02 Medicare Benefit Policy, Transmittal 165 (Dec. 21, 2012) ("progress reporting frequency . . . is being changed through this instruction.

Previously, the progress reporting was due every 10th treatment day or 30 calendar days, whichever was less. The new requirement is for the services related to the progress reports to be furnished on or before every 10th treatment day.”).

Regardless of the proper timing standard, a late progress report does not provide the OIG with a basis on which to deny payment. The MBPM provides that “[o]utpatient therapy services furnished to a beneficiary by a provider or supplier are payable only when furnished in accordance with certain conditions.” MBPM, Chapter 15, § 220.1. The MBPM then sets forth seven conditions of coverage, none of which relate to Progress Reports. *See id.*

Further:

contractors shall consider the entire record when reviewing claims for medical necessity so that the absence of an individual item of documentation does not negate the medical necessity of a service when the documentation as a whole indicates the service is necessary. Services are medically necessary if the documentation indicates they meet the requirements for medical necessity including that they are skilled, rehabilitative services, provided by clinicians (or qualified professionals when appropriate) with the approval of a physician/NPP, safe, and effective (i.e., progress indicates that the care is effective in rehabilitation of function).

MBPM, Chapter 15, § 220.3(A) (emphasis added).

Because CMS provides that a claim can be medically necessary even if an individual item of documentation is absent, the late submission of a progress report should not result in the denial of a claim. If CMS had intended for claims to be denied based on a missing progress report, it would not instruct contractors to consider the entire record, despite the absence of an individual item of documentation, when considering medical necessity. There would be no need to consider medical necessity in such a case if the absence of an item of documentation automatically resulted in payment denial.

The services in patient number 81’s case were medically necessary, so the failure to have a timely progress report should not cause the OIG to deny payment. *See* MBPM, Chapter 15, § 220.3(A). First, a Fox clinician performed the services. Second, they were provided with approval from a treating physician; patient number 81’s treating physician ordered the therapy services and certified the therapy plan of care. Third, the care was skilled because, by way of example only, the clinician progressed the patient’s program by adding or adjusting exercises throughout the course of care. *See* MBPM, Chapter 15, § 220.3(E) (explaining that adding new exercises or changing the exercise program demonstrates that services are skilled). Fourth, the services were safely provided because, for example, the clinician gave the patient consistent cues and assistance during strength and balance exercises, which prevented further back injury and falls during the performance of the exercises, and the clinician also gave the patient physical assistance and cueing for gait deviations to prevent falls while ambulating. Lastly, the services were effective because they addressed the patient’s deficiencies and the therapy benefitted the

patient, as her function did not decline and, in fact, she made improvements in strength, bed mobility, balance, and ambulation.

Thus, for these reasons, as well as the detailed explanation provided in Exhibit 10 attached hereto, the OIG improperly denied coverage to patient number 81.

H. "CODING DID NOT MEET MEDICARE REQUIREMENTS." CODING DID IN FACT MEET MEDICARE REQUIREMENTS.

The OIG's draft report claimed that Fox billed Medicare with an incorrect Healthcare Common procedure Coding System (HCPCS) code on one occasion, March 1, 2014 in the case of patient number 96. The OIG alleged that Fox billed for HCPCS code 97530 when it should have billed for HCPCS code 97535. The OIG is incorrect.

On March 1, 2014, the clinician clearly documented:

- upper body dressing, which was properly coded as one unit of 97535;
- bed mobility for two trials in combination with transfer training for five trials (both stand pivot and sit to stand transfers from a bed and a wheelchair), which was properly coded as two units of 97530;
- three therapeutic exercises, which were properly billed as one unit of 97110; and
- five manual therapy techniques, which were properly billed as 97140.

The OIG claimed that the two units of 97530 should not have been billed and, instead, three units of 97535 should have been billed. The OIG failed to recognize that both bed mobility and transfer training were properly billed as 97530. The Novitas Local Coverage Determination ("LCD") defines 97530 as:

. . . using functional activities (e.g., bending, lifting, carrying, reaching, catching and overhead activities) to improve functional performance. The activities are usually directed at a loss or restriction of mobility, strength, balance or coordination. They require the professional skills of a qualified professional and are designed to address a specific functional need of the patient. These dynamic activities must be part of an active treatment plan and directed at a specific outcome.

The bed mobility and transfer training were properly billed as 97530 because they satisfied the Novitas LDC billing guidance for that code. Specifically, bed mobility and transfer training use "functional activities (e.g., bending, lifting, . . .) to improve functional performance." Further, they were "directed at a loss or restriction of mobility, strength, balance or coordination." Upon evaluation, patient number 96 was found to have decreased shoulder and hip strength, as well as decreased shoulder range of motion. Also upon evaluation, patient

number 96 required total assistance with bathing, dressing, and toileting; required maximum assistance with bed mobility and transfers; minimum assistance with grooming and wheelchair mobility; and she was unable to ambulate. Lastly, the bed mobility and transfer training were “part of an active treatment plan and directed at a specific outcome.” The treating physician certified the plan of care, which included strength, range of motion, bed mobility, transfer, functional mobility, and training on activities of daily living. In conclusion, the clinician properly billed two units of 97530, and the OIG improperly found that three units of 97535 should be billed.

*I. “OTHER MATTERS: PLANS OF CARE NOT CERTIFIED IN A TIMELY MANNER.”
THE OIG SHOULD NOT INCLUDE ANY REFERENCE TO UNTIMELY
CERTIFICATIONS OF PLANS OF CARE IN ITS REPORT.*

As the OIG pointed out in its draft report, the physician signatures on some plans of care are dated later than 30 calendar days after the initial treatment provided under the plans. Under guidance provided by CMS, these delayed signatures satisfy the certification requirements for payment of a claim. See MBPM, Chapter 15, § 220.1.3(D).

Per the MBPM, “[d]elayed certification and recertification requirements shall be deemed satisfied where, at any later date, a physician/NPP makes a certification accompanied by a reason for the delay.” *Id.* Thus, it is not intended that reimbursement for therapy be denied when a certification is delayed. The example provided in the Manual advises that: “[p]ayment should not be denied, even when certified 2 years after treatment, when there is evidence that a physician approved needed treatment, such as an order . . . [or] requests for certification.” *Id.* See also ALJ Appeal No. 1-1053049918 (finding that delayed certification satisfied Medicare requirements for payment), a redacted copy of which is attached as Exhibit 11.

Fox produced executed physician orders for the therapy services provided to all 85 patients at issue. Additionally, Fox produced the plan of care tracking logs, which evidence Fox’s multiple attempts to have the physicians execute the plans of care within 30 calendar days after the initial treatment provided under the plans. Given these supporting documents, the delay in the physicians’ execution of these plans of care satisfies the Medicare certification requirements for payment of a claim. Because Fox satisfied the requirements of the Medicare program, the OIG’s report should not include a discussion about delayed certifications.

*J. THE OIG INCORRECTLY RELIED ON STATISTICAL EXTRAPOLATION TO
CONCLUDE THAT FOX SHOULD REPAY \$29.9 MILLION.*

*1) The OIG’s Reliance On Statistical Extrapolation Is Improper In
This Case.*

Statistical extrapolation is no substitute for the medical context that the treating physician and clinician rely upon in making treatment decisions for each Fox patient. Determining whether certain treatment was skilled, medically necessary, or appropriate cannot be made without reviewing and analyzing a patient’s documented medical history; age; disease(s) and

condition(s); number of medications and dosage amounts; adverse events (*e.g.*, falls, wounds, etc.); and other information.

Each patient for which Fox submits claims to CMS is under the care of a physician and a Fox clinician. As a result, the services provided are based on the medical judgment of two professionals. This medical judgment includes whether to provide therapy, which therapies to provide, how often to provide therapy, and when to discharge the patient. Determining the appropriate care to provide is highly individualized. In every case, the certifying physician and treating clinician must make a *subjective clinical* judgment regarding the patient's prognosis and the level of care required, thus making statistical extrapolation entirely inappropriate.

CMS has acknowledged that there are few bright-line rules for determining the need for services in a patient population comprised of elderly individuals. *See, e.g.*, 42 CFR § 409.32(c) ("The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities."). Similarly, according to the MBPM, "[d]eterminations as to whether medication¹⁶ is reasonable and necessary for an individual patient should be made *on the same basis as all other such determinations* (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and *the medical circumstances of the individual case*)." MBPM, Chapter 15, § 50.4.3 (emphasis added).

In considering the appropriateness of statistical extrapolation in the context of hospice services, a District Court acknowledged that "each and every claim at issue in this case is fact-dependent and wholly unrelated to each and every other claim." The District Court found that answering the medical-necessity question for each patient at issue required a "highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient." *See United States ex rel. Whitesides v. Agape Senior Community, Inc.*, Case No. 12-3466 (D.S.C. June 25, 2015), ECF No. 296 at 17-18.

Physician and clinician judgments are based on each Fox patient's unique condition and needs. They cannot be made by a mathematical formula. And some cases are physical therapy cases, some are occupational therapy cases, and others are speech therapy cases; thus, extrapolating from one discipline to another is an inappropriate attempt to compare apples and oranges. Consequently, the OIG's reliance on statistical extrapolation is improper in this case.

Further, the Social Security Act limits the use of extrapolation to cases in which the Secretary determines that: (1) there is a sustained or high level of payment error; or (2) documented educational intervention has failed to correct the payment error. The OIG failed to explain why it used extrapolation in the case. Regardless of the OIG's basis for extrapolation, neither of the required conditions apply here and, consequently, extrapolation is inappropriate. 42 U.S.C. § 1395ddd(f)(3).

¹⁶ Medicare coverage is available for "medical and other health services," which include certain medications. 42 U.S.C. § 1395k(a)(1); 42 U.S.C. § 1395x(s).

First, for the reasons set forth herein, as well as in the appendices hereto, the OIG cannot legitimately demonstrate that there is a sustained or high level of payment error in this audit. In fact, Fox has provided a legal and factual basis to reverse the findings in all 85 cases in which the OIG has claimed error.

Second, although Fox received audit findings in 2012 and 2013 that were “intended to be educational in regards to the appropriate submissions of Medicare claims,” these prior “educational” findings were based for the most part on the illegal “Improvement Standard” rejected by the *Jimmo* Court-ordered settlement in January 2013 and, therefore, cannot form the basis of any valid educational intervention.¹⁷ Additionally, through its compliance processes, Fox independently and proactively provides education and training to its clinicians. Education and training occurs at new employee orientations, as part of Fox’s compliance program, and at regular staff meetings. The OIG should provide credit to Fox for the education and training which Fox routinely provides to all clinicians.

In sum, both requisite conditions for extrapolation are lacking in this case, and the OIG cannot rely on extrapolation to determine the amount of any alleged payment error.

Finally, to the extent that the OIG begins recoupment based on extrapolation after Fox has appealed to a Qualified Independent Contractor, the OIG does so in violation of Fox’s Fifth Amendment right to Due Process. Without being afforded Due Process, Fox’s property will be unjustly taken and Fox will be irreparably harmed. There is no basis upon which to deny the 85 claims the OIG found to be unallowable. Before the OIG begins recoupment of properly submitted Medicare claims, Fox has the Due Process right to fully exhaust all five levels of appeal.

2) The OIG’s Method Of Extrapolation Is Statistically Flawed.

Attached hereto as Appendix C is the report of Frank Cohen, a statistical expert who reviewed the OIG’s method of extrapolation and determined that it was flawed. Fox incorporates Mr. Cohen’s arguments herein.

IV. CONCLUSION AND RESERVATION OF RIGHTS

As more fully explained above, the OIG’s use of the “Improvement Standard” to deny coverage to Fox’s patients violates the existing *Jimmo* Court Order as well as Medicare law and policy. Further, the denial of these claims represents a misapprehension of the unique nature of Fox’s patients and Fox’s mission of compliance. It is the very nature of Fox’s patient population—a frail geriatric population with significant co-morbidities—that compels medically necessary and skilled therapy pursuant to the order of a treating physician, as described more fully in the appendices hereto. To highlight the unique nature of Fox’s patient population and for a further description of the Fox mission, *see* Exhibits 12 and 13 attached hereto.

¹⁷ Although Fox recently received educational information from Novitas, any education from May 2017 cannot serve as the basis for allegedly failed educational intervention related to claims submitted in the audit period at issue, July 2013 to June 2015.

Without Fox's provision of skilled and medically necessary therapy, Medicare beneficiaries would be forced to turn to other care options, including expensive hospital stays. Treating beneficiaries in a hospital setting would only increase the costs borne by Medicare. Given the OIG's failure to follow Medicare law and policy, as well as its failure to consider the opinions of the patients' treating physicians as well as the individualized needs of the patients, the OIG's findings and conclusions for all 85 claims are erroneous. Fox thus requests that the OIG revise its draft report based on Fox's response.

Fox reserves the right to appeal all of the claims that were denied and reserves the right to provide additional information, documentation, and arguments¹⁸ for each denied claim at that time. Finally, to the extent that the OIG publishes its report or a portion thereof, the OIG should publish this opposition in its entirety.

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¹⁸ Fox reserves the right to assert additional arguments, including but not limited to the OIG's failure to properly respond to Fox's Freedom of Information Act Requests, as well as the bar against re-opening claims outside the statutory period.