

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDERI CARETENDERS HOME HEALTH
BILLED FOR HOME HEALTH SERVICES
THAT DID NOT COMPLY WITH
MEDICARE BILLING
REQUIREMENTS**

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Office of Inspector General

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Report in Brief

Date: August 2019

Report No. A-07-16-05092

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



Why OIG Did This Review

Under the Medicare home health prospective payment system (PPS), the Centers for Medicare & Medicaid Services pays home health agencies (HHAs) a standardized payment for each 60-day episode of care that a beneficiary receives. The PPS payment covers intermittent skilled nursing and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies.

Our prior reviews of home health services identified significant overpayments to HHAs. These overpayments were largely the result of HHAs improperly billing for services to beneficiaries who were not confined to the home (homebound) or were not in need of skilled services.

The objective of this review was to determine whether Mederi Caretenders (the Agency) complied with Medicare requirements for billing home health services.

How OIG Did This Review

We selected a stratified random sample of 100 home health claims (29 of these claims were for services in calendar year (CY) 2013 that were outside of the 4-year claim-reopening period). We evaluated the sampled claims for compliance with selected billing requirements and sent the claims to an independent medical review contractor to determine whether the services met coverage, necessity, and coding requirements.

Mederi Caretenders Home Health Billed for Home Health Services That Did Not Comply With Medicare Billing Requirements

What OIG Found

The Agency did not comply with Medicare billing requirements for 21 of the 71 home health claims paid in CYs 2014 or 2015 that we reviewed. For these claims, the Agency received overpayments of \$31,428. Specifically, the Agency incorrectly billed Medicare because (1) beneficiaries were not homebound, (2) beneficiaries did not require skilled services, (3) one claim was assigned with an incorrect Health Insurance Prospective Payment System billing code, or (4) one claim was not adequately documented. On the basis of our sample results, we estimated that during CYs 2014 and 2015 the Agency received overpayments totaling at least \$1.26 million.

What OIG Recommends and Agency Comments

We recommended that the Agency (1) refund to the Medicare program the portion of the \$1.26 million in estimated overpayments received during CYs 2014 and 2015 for claims incorrectly billed that are within the reopening and recovery periods; (2) exercise reasonable diligence to identify and return any additional similar overpayments outside of the 4-year claim-reopening period, in accordance with the 60-day rule; and (3) strengthen its controls to ensure full compliance with Medicare requirements for billing home health services.

The Agency disagreed with our findings and did not concur with any of our recommendations, including our extrapolated overpayment. The Agency stated that the draft report was fundamentally flawed because the independent medical review contractor misconstrued the applicable Medicare requirements and failed to perform a complete review of the patients' entire medical records. The Agency disputed our statistical sampling methodology and denied that the controls it had in place were inadequate to prevent the incorrect billing of Medicare claims. The Agency separately provided additional documentation related to these claims.

After reviewing the Agency's comments, the additional documentation that it provided, and the results of additional medical review, we revised our determinations, reducing the total number of reportable error claims in our audit period from 42 to 21, and revised our related findings and recommendations accordingly. We maintain that all of our findings, as revised, and all of our recommendations remain valid.

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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar year (CY) 2016, Medicare paid home health agencies (HHAs) about \$18 billion for home health services. The Centers for Medicare & Medicaid Services (CMS) determined through its Comprehensive Error Rate Testing (CERT) program that the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion. Although Medicare spending for home health care accounts only for about 5 percent of fee-for-service spending, improper payments to HHAs account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion). This review is part of a series of reviews of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements.

OBJECTIVE

Our objective was to determine whether Mederi Caretenders (the Agency) complied with Medicare requirements for billing home health services provided in CYs 2013, 2014, or 2015.

BACKGROUND

The Medicare Program and Payments for Home Health Services

Medicare Parts A and B cover eligible home health services under a prospective payment system (PPS). The PPS covers part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies. Under the home health PPS, CMS pays HHAs for each 60-day episode of care that a beneficiary receives.

CMS adjusts the 60-day episode payments using a case-mix methodology based on data elements from the Outcome and Assessment Information Set (OASIS). The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical severity, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcomes; and to determine whether adjustments to the case-mix groups are warranted. The OASIS classifies HHA beneficiaries into 153 case-mix groups that are used as the basis for the Health Insurance Prospective Payment System (HIPPS)

payment codes¹ and represent specific sets of patient characteristics.² CMS requires HHAs to submit OASIS data as a condition of payment.³

CMS administers the Medicare program and contracts with four of its Medicare administrative contractors (Medicare contractors) to process and pay claims submitted by HHAs.

Home Health Agency Claims at Risk for Incorrect Billing

In prior years, our reviews at other HHAs identified findings in the following areas:

- beneficiaries did not always meet the definition of “confined to the home,”
- beneficiaries were not always in need of skilled services,
- HIPPS billing codes were incorrectly billed, and
- billed services were not always adequately documented.

For the purposes of this report, we refer to these areas of incorrect billing as “risk areas.”

Medicare Requirements for Home Health Agency Claims and Payments

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act (the Act) § 1862(a)(1)(A)). Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act establish, and regulations at 42 CFR § 409.42 require, as a condition of payment for home health services, that a physician certify and recertify that the Medicare beneficiary is:

- confined to the home (homebound);
- in need of skilled nursing care on an intermittent basis, or physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and

¹ HIPPS payment codes represent specific sets of patient characteristics (or case-mix groups) on which payment determinations are made under several Medicare prospective payment systems, including those for skilled nursing facilities, inpatient rehabilitation facilities, and HHAs.

² The final payment is determined at the conclusion of the episode of care using the OASIS information but also factoring in the number and type of home health services provided during the episode of care.

³ 42 CFR §§ 484.20, 484.55, and 484.210(e); 74 Fed. Reg. 58077, 58110—58111 (Nov. 10, 2009); and CMS’s *Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1.

- receiving services under a plan of care that has been established and periodically reviewed by a physician.

Furthermore, as a condition for payment, a physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

The determination of “whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS as required by 42 CFR 484.55 or a medical record of the individual patient” (*Medicare Benefit Policy Manual* (the Manual), chapter 7, § 20.1.2). Coverage determination is not made solely on the basis of general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care (42 CFR § 409.44(a)).

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Providers that receive credible information of a potential overpayment must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).⁴

Appendix B contains the details of selected Medicare coverage and payment requirements for HHAs.

Mederi Caretenders⁵

The Agency is a home health care agency located in Creve Coeur, Missouri. CGS Administrators, LLC, its Medicare contractor, paid the Agency approximately \$26 million for 8,356 claims for services provided in CYs 2013, 2014, or 2015 (audit period) on the basis of CMS’s National Claims History (NCH) data.

⁴ The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

⁵ The Agency is owned by Caretenders Visiting Services of Saint Louis, LLC, and does business as Mederi Caretenders.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$24,860,805 in Medicare payments to the Agency for 7,189 claims for home health services that had dates of service in CYs 2013, 2014, or 2015. We selected a stratified random sample of 100 claims with payments totaling \$389,503 for review (29 of these claims were for services paid in CY 2013 that were outside of the 4-year claim-reopening period).⁶ We evaluated compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

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

Appendix A contains the details of our scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.⁷

FINDINGS

The Agency did not comply with Medicare billing requirements for 21 of the 71 home health claims paid in CYs 2014 or 2015 that we reviewed.^{8, 9} For these claims, the Agency received overpayments of \$31,428 for services paid in CYs 2014 or 2015.

Specifically, our medical reviewer determined that the Agency incorrectly billed Medicare for certain home health episodes, concluding:

- beneficiaries were not homebound,
- beneficiaries did not require skilled services,

⁶ 42 CFR § 405.980(b)(2).

⁷ Sample items may have more than one type of error.

⁸ We identified six other home health claims for CYs 2014 and 2015 that did not comply with Medicare billing requirements, but are not reporting on those claims because they had no effect on overpayments.

⁹ At the time that we issued our draft report to the Agency, all claims for home health services provided in CY 2013 were outside of the 4-year claim-reopening period. Therefore, we did not report on those claims. However, we made the Agency aware that it did not comply with Medicare billing requirements for 13 of the 29 home health claims for home health services provided in CY 2013 that we reviewed.

- claims contained incorrect HIPPS billing codes, or
- documentation was missing or insufficient to support the services the Agency provided.

These errors occurred primarily because the Agency did not have adequate controls to prevent the incorrect billing of Medicare claims.

On the basis of our sample results, we estimated that during CYs 2014 and 2015 the Agency received overpayments totaling at least \$1,262,887.¹⁰ As of the publication of this report, this amount included claims outside of the 4-year claim-reopening period.

Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.

AGENCY BILLING ERRORS

The Agency incorrectly billed Medicare for 21 of the 71 sampled claims for services paid in CYs 2014 or 2015 that we reviewed, which resulted in overpayments of \$31,428. (Some sampled claims had more than one type of error.)

Beneficiaries Were Not Homebound

Federal Requirements for Home Health Services

For the reimbursement of home health services, the beneficiary must be “confined to the home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42)). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

¹⁰ 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 95 percent of the time.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 1 of section 30.1.1 (effective October 1, 2003), Revision 172 of section 30.1.1 (effective November 19, 2013), and Revision 208 of section 30.1.1 (effective January 1, 2015) covered different parts of our audit period.¹¹

Revision 1 states that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home. An individual does not have to be bedridden to be considered confined to the home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort. Generally speaking, patients will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

Revisions 172 and 208 state that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home and an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criterion One

The patient must either:

- because of illness or injury, need the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence; or
- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criterion One conditions, then the patient must also meet two additional requirements defined in Criterion Two below.

Criterion Two

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

¹¹ Coverage guidance is identical in Versions 172 and 208 of § 30.1.1. The only differences are minor revisions to a few examples.

The Agency Did Not Always Meet Federal Requirements for Home Health Services

For 15 of the sampled claims, our medical reviewer determined that the Agency incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above criteria for being homebound.¹²

Example 1: Beneficiary Not Homebound – Entire Episode

Documentation for one beneficiary did not support that the patient was homebound, because the patient had independent mobility without use of an assistive device and had (according to the documentation) no weight-bearing precautions or history of recent falls. Additionally, the beneficiary was alert and oriented without cognitive difficulties and had around-the-clock caregivers to provide assistance if needed. Thus, leaving the home would not have required a considerable and taxing effort.

Beneficiaries Did Not Require Skilled Services

A Medicare beneficiary must be in need of skilled nursing care on an intermittent basis, or physical therapy or speech-language pathology, or have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1895n(a)(2)(A) and Federal regulations (42 CFR § 409.42(c)). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).¹³ Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care 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 (the Manual, chapter 7, § 20.1.2).

¹² Of these 15 claims with homebound errors, 4 claims were also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

¹³ Skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

For eight of the sampled claims, our medical reviewer determined that the Agency incorrectly billed Medicare for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.¹⁴

Example 2: Beneficiary Did Not Require Skilled Services

On one claim, the beneficiary had nonskilled wound care needs and had a caregiver available who demonstrated the dressing changes correctly at the start of the recertification period and who was performing the wound care in the skilled nurse's absence. Therefore, skilled nursing care was not reasonable and necessary to the treatment of this beneficiary's injury.

Incorrectly Billed Health Insurance Prospective Payment System Billing Code

Medicare payments may not be made for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act § 1862(a)(1)(A)). CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, states: "In order to be processed correctly and promptly, a bill must be completed accurately" (chapter 1, § 80.3.2.2).

For one of the sampled claims, our medical reviewer determined that the Agency billed Medicare with an incorrectly coded claim that resulted in a higher HHA claim payment to the Agency. Specifically, a HIPPS code was not supported in the medical records.

Missing or Insufficient Documentation

A physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (the Act § 1833(e)).

For one of the sampled claims, our medical reviewer determined that the Agency incorrectly billed Medicare for a home health episode that did not meet Medicare documentation requirements. This claim lacked adequate documentation of a face-to-face patient encounter with a physician or an allowed nonphysician practitioner.

¹⁴ Of these eight claims with skilled need service that were not medically necessary, the Agency billed four of the claims for beneficiaries with homebound errors. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that during CYs 2014 and 2015 the Agency received overpayments totaling at least \$1,262,887.

RECOMMENDATIONS

We recommend that the Agency:

- refund to the Medicare program the portion of the \$1,262,887 in estimated overpayments received during CYs 2014 and 2015 for claims incorrectly billed that are within the reopening and recovery periods;¹⁵
- exercise reasonable diligence to identify and return any additional similar overpayments outside of the 4-year claim-reopening period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen its controls to ensure full compliance with Medicare requirements for billing home health services.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Agency, through its attorneys, disagreed with our findings and did not concur with any of our recommendations, including our extrapolated overpayment. The Agency stated that the draft report was “fundamentally flawed” because the independent medical review contractor misconstrued the applicable provisions of the Manual and failed to perform a complete review of the patients’ entire medical records. The Agency also characterized our statistical sampling methodology as “flawed and unreliable” and did not concur with our second recommendation regarding the identification and return of similar overpayments outside the 4-year claim reopening period. In this regard, the Agency said that it already had effective policies and procedures in place to identify and return overpayments within 60 days in the ordinary course of business. With respect to our third

¹⁵ Office of Inspector General (OIG) audit recommendations do not represent final determinations by the Medicare program but are recommendations to U.S. Department of Health and Human Services action officials. Action officials at CMS, acting through a Medicare contractor or other contractor, will determine whether an overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

recommendation, the Agency denied that the controls it had in place were inadequate to prevent the incorrect billing of Medicare claims.

The Agency separately provided additional documentation related to the claims that our draft report had questioned and enclosed a consultant's report which, the Agency said, demonstrated the errors in our statistical sampling methodology.

To address the Agency's concerns, we requested that our independent medical review contractor review the Agency's written comments on our draft report and the supplemental documentation that it provided.

Based on the results of this review, we revised our determinations, reducing the total number of reportable error claims for services paid in CYs 2014 and 2015 from 42 to 21, and revised our related findings and recommendations accordingly. We maintain that our remaining findings and recommendations are valid, although we acknowledge the Agency's rights to appeal the findings. Below is a summary of the reasons the Agency did not agree with our findings and recommendations as well as our responses.

The Agency's comments, from which we have removed various enclosures due to their volume and because some of them contain proprietary information, appear as Appendix F. We are providing the Agency's comments in their entirety to CMS.

BENEFICIARIES WHO WERE NOT HOMEBOUND

Auditee Comments

The Agency disagreed with all of our findings related to homebound status and stated that a patient need not be bedridden to be considered homebound. "Rather, the condition of the patient must be such that leaving home was not recommended A patient may be homebound and still leave the home for needed medical treatment and short, infrequent non-medical reasons. Homebound status must be determined on a case-by-case basis."

The Agency cited several examples of claims that we had questioned but which involved beneficiaries who were, according to the Agency, homebound under applicable Medicare regulations and guidance, to include the Manual. In many instances, the Agency said, "it is clear the independent medical review contractor did not consider the entire medical record but instead latched on to any single episode in the record showing the patient doing well" as evidence that the beneficiary in question was not homebound. For another beneficiary ("Patient 42"), the Agency described various cognitive issues "all of which impacted on her ability to safely leave the home The patient used a cane and required stand-by assistance"

Office of Inspector General Response

Based on the information that the Agency provided and the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to homebound status (and the associated recommended disallowance) to specify that 15 claims, rather than 33, involved beneficiaries who did not meet the criteria for being homebound.

We disagree with the Agency's assertion that our medical reviewer did not consider the entire medical record. Our medical reviewer prepared detailed medical review determination reports that documented relevant facts and the results of their analysis. These were provided to the Agency before we issued our draft report. Each determination letter included a detailed set of facts based on a thorough review of the entire medical record. In all cases, our medical reviewer considered the entire record and relied on the relevant and salient facts necessary to determine homebound status in accordance with CMS's homebound definition.

Ambulation distance is one factor among others that our medical reviewer considered in making determinations of homebound status. As shown in each medical review determination report, our medical reviewer documented in detail and reviewed the relevant medical history—including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility—for each beneficiary. In terms of meeting CMS homebound criteria, medical review determinations must be based on each patient's individual characteristics as reflected in the available medical record. Our medical reviewer carefully considered the ability to ambulate in conjunction with the individual characteristics noted in each patient's medical record. Ambulation distance is not noted in all decisions, and when it is, it is simply one factor that the reviewer considered in making the homebound determination. This is evident from the relevant facts and discussion included in the individual determinations.

As set forth in the Manual, chapter 7, section 30.1.1,¹⁶ the second requirement for being homebound is that there must exist a normal inability to leave home and that leaving the home must require a considerable and taxing effort. CMS guidance provides the following example of a homebound patient, which references the physical characteristics of the living environment: "Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists would be A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence" (the Manual, chapter 7, § 30.1.1).

Physical barriers in the home environment are relevant to the homebound assessment under the "normal inability" and "considerable and taxing effort" requirement (Criterion Two). Although the patient is the focus of the homebound requirement, the lack of physical access

¹⁶ This refers to the post-Change Request 8444/Transmittal 172 version of the Manual that we applied to beneficiaries for claims with dates of service on or after November 19, 2013.

barriers in an assisted living facility, as in a private residence, is a factor in determining whether a beneficiary is homebound under Criterion Two. For example, a patient residing in a walk-up but who no longer can negotiate steps or stairs has a “normal inability” to leave home, and leaving a home with that physical characteristic would require a “considerable and taxing effort.” This may not be the case for the same patient in a residence without steps or stairs. The physical characteristics of the home environment, however, are always considered along with the patient's condition.¹⁷

CMS guidance mentions that a patient may have multiple residences and states that homebound status must be met at each residence (the Manual, chapter 7, § 30.1.2). CMS states the following (emphasis added):

A patient may have more than one home and the Medicare rules do not prohibit a patient from having one or more places of residence. A patient, under a Medicare home health plan of care, who resides in more than one place of residence during an episode of Medicare covered home health services will not disqualify the patient’s homebound status for purposes of eligibility. For example, a person may reside in a principal home and also a second vacation home, mobile home, or the home of a caretaker relative. The fact that the patient resides in more than one home and, as a result, must transit from one to the other, is not in itself, an indication that the patient is not homebound. **The requirements of homebound must be met at each location (e.g., considerable taxing effort etc.)** (the Manual, chapter 7, § 30.1.2).

CMS anticipated that the physical characteristics of a patient’s residence could impact the homebound determination under Criterion Two. Accordingly, it can be reasonably inferred that CMS expects the physical characteristics of a given residence to impact the homebound analysis under Criterion Two. Thus, contrary to the Agency’s assertions, it was not an error for our medical reviewer to consider the physical characteristics of the home environment as one of many factors in making homebound determinations.

The Agency also asserted that leaving the home for short infrequent trips does not preclude a patient from qualifying as homebound. While some medical review decisions do note that patients on occasion left the home, this factor was not dispositive of a homebound finding unless the patient was regularly and routinely leaving the home.

¹⁷ Regarding physical environment characteristics that beneficiaries may encounter once they leave the home, Title III of the Americans with Disabilities Act of 1990 (ADA), as amended (codified at 42 U.S.C. §§ 12181-12189), and its implementing regulations (28 CFR part 36), prohibits discrimination on the basis of disability in the activities of places of public accommodation (that is, businesses that are generally open to the public and that fall into 1 of 12 categories listed in the ADA, such as restaurants, movie theaters, schools, daycare facilities, recreation facilities, and doctors’ offices) and requires newly constructed or altered places of public accommodation—as well as commercial facilities (privately owned, nonresidential facilities)—to comply with the ADA standards.

In the Manual, chapter 7, section 30.1.1, CMS states:

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration.

This is the guidance that our independent medical review contractor followed in its reviews.

The Agency also stated that the medical review contractor failed to adequately consider many beneficiaries' cognitive limitations when making homebound determinations. We agree that cognitive impairment must be considered in making a homebound determination. Our medical review contractor carefully considered the patients' cognitive function in conjunction with the individual characteristics noted in each patient's medical record. Cognitive impairment is one factor among others that our medical review contractor considered in making homebound determinations.

Rather than "latching onto" isolated episodes in the beneficiaries' medical records, as the Agency contended in its written comments, the foregoing discussion underscores that the medical review contractor examined all of the material in those records and the documentation submitted by the Agency and carefully considered this information to determine whether the Agency billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that the Agency provided after issuance of our draft report. For all medical review, the independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. For example, with respect to Patient 42, the most recent determination by our independent medical review contractor noted, "Although she had

posture and gait deviations, she was able to ambulate without an assistive device” and added, “Her condition was noted to be stable at the start of care”

Accordingly, having revised our findings and the associated recommendation with respect to 18 of the claims identified in our draft report, we maintain that our findings for the remaining 15 claims, and the revised recommendation, are valid.

BENEFICIARIES WHO DID NOT REQUIRE SKILLED SERVICES

Auditee Comments

The Agency disagreed with all of our findings related to skilled services and cited several examples in which, it said, the independent medical review contractor failed to consider the entirety of the patient’s medical record. The Agency pointed to other cases in which the independent medical review contractor determined that skilled therapy was no longer necessary after a certain date, because the patient had reached his or her functional plateau. According to the Agency, though, the beneficiaries showed continued progress after those dates. In this regard, the Agency pointed to one beneficiary (“Patient 60”) who, according to our draft report’s findings, no longer needed physical therapy after May 26, but who had suffered a fall with injuries on June 18.

Office of Inspector General Response

Based on the information that the Agency provided and the conclusions of our independent medical review contractor’s additional medical review, we revised our findings related to skilled services (and the associated recommended disallowance) to specify that 8 claims, rather than 17, involved beneficiaries who did not meet the criteria for Medicare coverage of skilled nursing or therapy services.

Our medical review contractor’s determinations of the medical necessity of skilled therapy services were made in accordance with the Manual, chapter 7, section 40.2. In accordance with these CMS guidelines, it is necessary to determine whether individual therapy services are skilled and whether, in view of the patient’s overall condition, skilled management of the services provided is needed. The guidelines also state that although a patient’s particular medical condition is a valid factor in deciding whether skilled therapy services are needed, a patient’s diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel. The skilled therapy services must be reasonable and necessary to the treatment of the patient’s illness or injury within the context of the patient’s unique medical condition.

Skilled nursing services can include observation and assessment of a patient’s condition (the Manual, chapter 7, § 40.1.2). In determining the medical necessity of skilled nursing for observation and assessment, our medical review contractor considered the reasonable

potential of a change in condition, complication, or further acute episode (e.g., high risk of complications) under the provisions of the Manual, chapter 7, section 40.1.2.1.

Rather than failing to consider the entirety of the beneficiaries' medical records, the medical review contractor examined all of the material in those records and the documentation submitted by the Agency and carefully considered this information to determine whether the Agency billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that the Agency provided after issuance of our draft report. For all medical review, the independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. With respect to Patient 60, for example, our independent medical review contractor determined that "[s]killed physical therapy was indicated at the start of care for mobility and strength training and to establish a maintenance home exercise program. However, as of 5/26/2015, he was independently performing his home exercise program. A daily home exercise program with assistance from his nonskilled caregivers if needed, would have met this patient's needs without required ongoing skilled physical therapy."

Accordingly, having revised our findings and the associated recommendation with respect to nine of the claims identified in our draft report, we maintain that our findings for the remaining eight claims, and the revised recommendation, are valid.

CLAIMS WITH INCORRECTLY BILLED HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM BILLING CODES

Auditee Comments

The Agency disagreed with all of our findings related to billing code errors. As one example, the Agency said that the independent medical review contractor erred in determining that claims associated with Patient 51 were incorrectly coded. The Agency added that in another instance (Patient 85), the independent medical review contractor used a minor clerical error, in which a single data field had been "inadvertently skipped," to deny a claim for supposed lack of medical necessity. The Agency pointed out that the independent medical review contractor also concluded for that same patient that the physical and occupational therapy that the Agency provided was medically necessary. "The inconsistency in these conclusions shows that this is at most a minor clerical error which should not be used as a basis for denying the patient's claim."

Office of Inspector General Response

Based on the information that the Agency provided and the conclusions of our independent medical review contractor's additional medical review, we revised our findings related to billing code errors (and the associated recommended disallowance) to specify that one claim, rather than five, involved incorrectly billed HIPPS billing codes. (We removed the findings associated with both Patient 51 and Patient 85 from this final report.) The medical review contractor examined all of the material in the medical records and the documentation submitted by the

Agency and carefully considered this information to determine whether the Agency billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that the Agency provided after issuance of our draft report. For all medical review, the independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. In the case of these billing code errors, the independent medical review contractor determined, after its additional medical review, that one claim (Patient 2) remained in error. We note that the Agency provided no information or documentation in its written comments on our draft report that would cause us to revise our finding for this claim. We therefore maintain that our finding for this claim, and the revised recommendation, are valid.

CLAIMS WITH MISSING DOCUMENTATION

Auditee Comments

The Agency disagreed with our finding that one of the sampled claims did not meet Medicare documentation requirements. The Agency said that “there was only a single claim that was found to lack sufficient documentation” and added that “[t]he single discrepancy involving a missing face to face [encounter] form should not be used to deny payment for the quality skilled care [the patient] received, which led to an improvement in his functional ability.” The Agency also described other documentation that did exist and that supported, it said, that there were communications between the certifying physician and the patient’s physical therapist.

Office of Inspector General Response

We maintain that our finding for this claim remains valid. Although the Agency cited various forms of documentation that existed, it also acknowledged that this claim lacked sufficient documentation. The most recent determination by our independent medical review contractor noted, “the home health certification and plan of care [were] not valid as there was no face to face documentation evident.”

USE OF STATISTICAL SAMPLING

Auditee Comments

The Agency described the statistical sampling methodology that led to our recommended disallowance as “fundamentally flawed and an unreliable basis for extrapolation.” The Agency gave us, as part of its additional documentation (an enclosure to its written comments), a report from an outside consultant, “which demonstrates the errors in the OIG’s statistical sampling methodology.” The consultant’s report states that our statistical methods are invalid because of the choice of sample design and sample size, the distribution of the sample mean, the potential differences between the sample and the frame it was drawn from, the failure to draw an initial probe sample (i.e., a smaller test sample), and other issues. Because the Agency

marked this consultant's report "confidential," we are not including it as part of Appendix F but will provide it to CMS.

Office of Inspector General Response

We carefully reviewed the documentation that the Agency provided (the consultant's report) regarding our sampling and estimation methods, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by the Federal Government to the Agency.

Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid. See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (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).

The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. 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); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634–37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012). We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. Our methodology accounts for the difference between the sample and the sampling frame and for the potential non-normal distribution of the sample mean.

To account for the potential differences between the sample and the sampling frame, we recommend recovery at the statistical lower limit of a two-sided 90-percent confidence interval.¹⁸ Lower limits calculated in this manner are designed to be less than the actual overpayment in the sampling frame 95 percent of the time. The use of the lower limit accounts for both the sample design and sample size in a manner that favors the auditee. See *Puerto Rico Dep't of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the

¹⁸ The Agency performed a statistical test whose stated purpose was to show that the sample was "not representative of the universe." We do not agree that such tests are necessary. However, given that such tests are performed, they must account for the weighting used in selecting the sample. We replicated the analysis performed by the Agency and found that it did not account for the weighting. When the weighting was accounted for, the anomalies identified by the Agency disappeared.

confidence interval gave the State the “benefit of any doubt” raised by use of a smaller sample size).

The Agency contended that the validity of the lower limit could be impacted by the potential non-normality of the sample mean. To address this point, we compared our original approach against an alternative, known as the empirical likelihood method, that does not assume normality. The lower limit calculated using the empirical likelihood method was higher than our original calculation.¹⁹ This result is not surprising given that the normal approximation is known to be conservative in situations like the current one in which the overpayment amounts are positively skewed.

IDENTIFICATION AND RETURN OF SIMILAR OVERPAYMENTS OUTSIDE OF THE 4-YEAR CLAIM-REOPENING PERIOD IN ACCORDANCE WITH THE 60-DAY RULE

Auditee Comments

The Agency did not concur with our recommendation that it exercise reasonable diligence to identify and return any additional similar overpayments outside of the 4-year claim-reopening period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with that recommendation. The Agency disagreed with this second recommendation because it disagreed that it had received any overpayments. The Agency said that it already had effective policies and procedures in place to identify and return overpayments within 60 days in the ordinary course of business.

Office of Inspector General Response

We maintain that all of our findings, as revised, are valid, for the reasons given above in our responses to the Agency’s other comments and for the reasons given earlier in our findings themselves. These reasons are well supported by the legal criteria we have cited and by our independent medical review contractor’s determinations. Therefore, we maintain that our second recommendation, regarding the identification and return of similar overpayments outside of the 4-year claim-reopening period, remains valid as well.

¹⁹ The empirical likelihood approach resulted in a lower limit of \$1,422,679, which was higher than the \$1,262,887 that we calculated using RAT-STATS.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$24,860,805 in Medicare payments to the Agency for 7,189 claims for home health services that had dates of service in CYs 2013, 2014, or 2015. At the time that we issued our draft report to the Agency, all claims for home health services provided in CY 2013 were outside of the 4-year claim-reopening period. However, we made the Agency aware that it did not comply with Medicare billing requirements for 13 home health claims for services paid in CY 2013 that we reviewed and that were outside of the 4-year claim-reopening period. We selected for review a stratified random sample of 100 home health claims with payments totaling \$389,503.

We evaluated compliance with selected billing requirements and submitted the sampled claims to an independent medical review to determine whether the services met medical necessity and coding requirements.

We limited our review of the Agency's internal controls to those applicable to specific Medicare billing procedures because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

We conducted our audit work from February 2016 through June 2017.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Agency's paid claims data from CMS's NCH file for the audit period;
- selected a stratified random sample of 100 home health claims totaling \$389,503 for detailed review (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed billing and medical record documentation provided by the Agency to support the selected claims;

- used an independent medical review contractor to determine whether the claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate, for CYs 2014 and 2015, the Medicare overpayments to the Agency (Appendix D);
- identified 29 home health claims for services paid in CY 2013 that were outside of the 4-year claim-reopening period;
- discussed the results of our review with Agency officials on June 28, 2017; and,
- after receiving the Agency's written comments on our draft report, asked the independent medical review contractor to perform an additional medical review of all of the claims that our draft report had questioned, and incorporated those results into our own analysis and determination of the allowability of the claims in light of the Agency's comments and the supplemental documentation it provided.

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: MEDICARE REQUIREMENTS FOR COVERAGE AND PAYMENT OF CLAIMS FOR HOME HEALTH SERVICES

GENERAL MEDICARE REQUIREMENTS

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)).

CMS’s Medicare Claims Processing Manual, Pub. No. 100-04, states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

OUTCOME AND ASSESSMENT INFORMATION SET DATA

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcome; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries can be classified into 153 case-mix groups that are used as the basis for the HIPPS payment codes Medicare uses in its prospective payment systems. Case-mix groups represent specific sets of patient characteristics and are designed to classify patients who are similar clinically in terms of resources used.

CMS requires the submission of OASIS data as a condition of payment as of January 1, 2010 (42 CFR §§ 484.20, 484.55, and 484.210(e); 74 Fed. Reg. 58078, 58110 (Nov. 10, 2009); and *CMS’s Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1).

COVERAGE AND PAYMENT REQUIREMENTS

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy or speech-language pathology, or occupational therapy;²⁰ (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

²⁰ Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, physical therapy service, or speech language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68526, 68590 (Nov. 4, 2011)).

According to the Manual, chapter 7, section 20.1.2, whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS, or a medical record of the individual patient.

Furthermore, as a condition for payment, a physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)).

Section 6407(a) of the Affordable Care Act²¹ added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care by including the date of the encounter.²²

Confined to the Home

For the reimbursement of home health services, the beneficiary must be “confined to the home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42)). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 1 of section 30.1.1 (effective October 1, 2003), Revision 172 of section 30.1.1 (effective

²¹ The Patient Protection and Affordable Care Act, P.L. No. 111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

²² See 42 CFR § 424.22(a) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

November 19, 2013), and Revision 208 of section 30.1.1 (effective January 1, 2015) covered different parts of our audit period.²³

Revision 1 states that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home. An individual does not have to be bedridden to be considered confined to the home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving home would require a considerable and taxing effort. Generally speaking, patients will be considered to be homebound if they have a condition due to an illness or injury that restricts their ability to leave their place of residence except with the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.

Revisions 172 and 208 state that for a patient to be eligible to receive covered home health services under both Medicare Parts A and B, the law requires that a physician certify in all cases that the patient is confined to his or her home and an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

Criterion One

The patient must either:

- because of illness or injury, need the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence; or
- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criterion One conditions, then the patient must also meet two additional requirements defined in Criterion Two below.

Criterion Two

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

²³ Coverage guidance is identical in Versions 172 and 208 of § 30.1.1. The only differences are minor revisions to a few examples.

Need for Skilled Services

Intermittent Skilled Nursing Care

To be covered as skilled nursing services, the services must require the skills of a registered nurse, or a licensed practical (vocational) nurse under the supervision of a registered nurse; must be reasonable and necessary to the treatment of the patient's illness or injury; and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).

The Act defines "part-time or intermittent services" as skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours each week) (the Act § 1861(m) and the Manual, chapter 7, § 50.7).

Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement, but rather on the patient's need for skilled care. Skilled care 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 (the Manual, chapter 7, § 20.1.2).

Requiring Skills of a Licensed Nurse

Federal regulations (42 CFR § 409.44(b)) state that in determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice. If the nature of a service is such that it can be safely and effectively performed by the average nonmedical person without direct supervision of a licensed nurse, the service may not be regarded as a skilled nursing service. 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. If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

General Principles Governing Reasonable and Necessary Skilled Nursing Care

Skilled nursing services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a registered nurse or licensed practical (vocational) nurse are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided.

Some services may be classified as a skilled nursing service on the basis of complexity alone (e.g., intravenous and intramuscular injections or insertion of catheters) and, if reasonable and necessary to the patient's illness or injury, would be covered on that basis. If a service can be safely and effectively performed (or self-administered) by an unskilled person, without the direct supervision of a nurse, the service cannot be regarded as a skilled nursing service even though a nurse actually provides the service. However, in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse. A service is not considered a skilled service merely because it is performed by or under the supervision of a nurse. The unavailability of a competent person to provide a nonskilled service does not make it a skilled service when a nurse provides the service.

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the patient needs is either skilled or not skilled. Skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable (the Manual, chapter 7, § 40.1.1).

Reasonable and Necessary Therapy Services

Federal regulations (42 CFR § 409.44(c)) and the Manual (chapter 7, § 40.2.1) state that skilled services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition. To be considered reasonable and necessary for the treatment of the illness or injury, the therapy services must be:

- inherently complex, which means that they can be performed safely and effectively only by or under the general supervision of a skilled therapist;
- consistent with the nature and severity of the illness or injury and the patient's particular medical needs, which include services that are reasonable in amount, frequency, and duration; and
- considered specific, safe, and effective treatment for the patient's condition under accepted standards of medical practice.

Documentation Requirements

Face-to-Face Encounter

Federal regulations (42 CFR § 424.22(a)) and the Manual (chapter 7, § 30.5.1) state that, prior to initially certifying the home health patient's eligibility, the certifying physician must

document that he or she, or an allowed nonphysician practitioner, had a face-to-face encounter with the patient that is related to the primary reason the patient requires home health services. A physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (the Act § 1833(e)).

Plan of Care

The orders on the plan of care must indicate the type of services to be provided to the patient, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services (the Manual, chapter 7, § 30.2.2). The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient's plan of care must contain the signature of the physician and the date of review (42 CFR § 409.43(e) and the Manual, chapter 7, § 30.2.6).

APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consists of the Agency's claims for selected home health services that it provided to Medicare beneficiaries during CYs 2013, 2014, and 2015.

SAMPLING FRAME

The sampling frame consisted of a database of 7,189 home health claims, valued at \$24,860,805, from CMS's NCH file.²⁴

SAMPLE UNIT

The sample unit was a home health claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into three strata based on claim payment amounts.

Stratum	Dollar Range of Frame Units	Number of Frame Units	Sample Size	Dollar Value of Frame Units
1	\$1,038.16 to \$3,177.99	3,600	34	\$8,213,784.67
2	\$3,178.00 to \$4,859.26	2,073	33	8,254,420.45
3	\$4,859.27 and higher	1,516	33	8,392,600.03
	Totals	7,189	100	\$24,860,805.15

SAMPLE SIZE

We randomly selected 34 unique HHA claims from stratum 1, 33 from stratum 2, and 33 from stratum 3. Our total sample size was therefore 100 home health claims.

SOURCE OF RANDOM NUMBERS

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

²⁴ Our sampling frame excluded claims associated with (1) type of bill 322 (request for anticipated payment), (2) paid claims of \$1,000 or less, and (3) 11 claims associated with error code 534 (claims that are excluded from further review, such as Recovery Audit Contractor-reviewed claims).

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the frame from 1 to 3,600 for stratum 1; from 1 to 2,073 for stratum 2; and from 1 to 1,516 for stratum 3. A statistical specialist generated 34 random numbers for stratum 1 and 33 random numbers each for strata 2 and 3. With these random numbers, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to estimate the total amount of Medicare overpayments that were made to the Agency for claims listed within our sample frame and that were paid in CYs 2014 or 2015. 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 in the sampling frame 95 percent of the time.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

**OVERALL SAMPLE RESULTS
FOR 2014 AND 2015 CLAIMS**

Stratum	Incorrectly Billed Sample Items²⁵	Value of Overpayments In Sample
1	6	\$9,544
2	10	12,917
3	5	8,967
Total	21	\$31,428

ESTIMATES

**Estimate of Overpayments for the Audit Period
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$2,233,935
Lower limit	\$1,262,887
Upper limit	\$3,204,983

²⁵ We identified six other home health claims for CYs 2014 and 2015 that did not comply with Medicare billing requirements. We are not reporting on the details of those six claims because they had no effect on overpayments.

APPENDIX E: TYPES OF ERRORS, BY SAMPLE ITEM, FOR 2014 AND 2015²⁶

STRATUM 1

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment
1					-
2			X		\$1,681.03
3					-
4					-
5					-
6					-
7					-
8					-
<u>9</u>					-
<u>10</u>					-
11					-
12					-
13					-
14					-
15					-
<u>16</u>					-
17					-
<u>18</u>					-
19					-
20					-
21	X	X			2,465.71
22					-
23					-
24					-
25	X	X			547.19
26					-
27					-
28	X	X			863.81
29	X	X			3,041.68
30					-
31		X			944.76
<u>32</u>					-
33					-
34					-

²⁶ We also made the Agency aware that it did not comply with Medicare billing requirements for 13 home health claims for services in CY 2013 that we reviewed. These claims' sample numbers are underlined; the claims are not included in the table totals for this Appendix.

STRATUM 2

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment/ Underpayment
35					-
36					-
37					-
38					-
39					-
40	X				\$1,020.04
41	X				965.87
42	X				3,416.11
43					-
44	X				629.84
45					-
46					-
47					-
48					-
49	X				1,433.42
50	X				-353.81
51					-
52					-
53					-
54					-
55					-
56					-
57		X			1,994.96
58					-
59	X				953.59
60		X			1,762.54
61					-
62					-
63					-
64					-
65					-
66	X				1,094.54
67					-

STRATUM 3

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment
68	X				\$535.72
69					-
<u>70</u>					-
<u>71</u>					-
72					-
73					-
74	X				476.42
75					-
<u>76</u>					-
77					-
78		X			2,067.69
79					-
80					-
81				X	5,405.98
82					-
83					-
84					-
85					-
86					-
87					-
<u>88</u>					-
89					-
90					-
91	X				481.35
92					-
<u>93</u>					-
94					-
95					-
96					-
97					-
98					-
99					-
100					-
Totals for 2014 and 2015	15	8	1	1	\$31,428.44



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April 16, 2018

Patrick J. Cogley
 Regional Inspector General for Audit Services
 Department of Health and Human Services
 Office of the Inspector General
 Office of Audit Services, Region VII
 601 East 12th Street, Room 0429
 Kansas City, MO 64106

Re: Report Number: A-07-16-0592, *Mederi Caretenders*

Dear Mr. Cogley:

I am counsel for Caretenders Visiting Services of St. Louis, LLC d/b/a Mederi Caretenders. Thank you for considering this response to the draft report, "*Mederi Caretenders Home Health Billed for Home Health Services That Did Not Comply With Medicare Billing Requirements*" ("Draft Report"). For the reasons set forth below, Mederi Caretenders disagrees with the findings of the independent medical review contractor that the audited claims did not meet Medicare billing requirements. For each of the forty-two denied claims, Mederi Caretenders is submitting detailed responses which demonstrate that the patients at issue were in fact homebound and had skilled needs, and were provided quality care from Mederi Caretenders that was reasonable and medically necessary, correctly coded and properly documented. Mederi Caretenders contends that the Draft Report is fundamentally flawed because the independent medical review contractor misconstrued the applicable Medicare Benefit Policy Manual provisions and failed to perform a complete review of the patients' entire medical record. Mederi Caretenders had requested the opportunity to meet with the independent medical review contractor during the course of the audit to address these shortcomings, but that request was denied. We continue to believe that such a meeting would have improved the accuracy of the Draft Report, and welcome such dialogue in the future in the hopes that these errors can be corrected before the issuance of a final report.

Mederi Caretenders further contends that the statistical sampling methodology that led to the extrapolated overpayment of \$5,251,925 is flawed and unreliable. We are also enclosing the expert report of Stefan Boedeker of Berkeley Research Group, which demonstrates the errors in the OIG's statistical sampling methodology. For these reasons, Mederi Caretenders maintains that no overpayment exists, as alleged in the Draft Report, and that all forty-two of the denied claims were properly reimbursed by Medicare. Mederi Caretenders further denies the contention in the Draft Report that it did not have adequate controls in place to prevent the incorrect billing of Medicare claims. The accuracy and appropriateness of all of the audited claims shows that Mederi Caretenders has effective policies and procedures in place to ensure correct Medicare

billing. Mederi Caretenders' response to the internal control questionnaire further underscores this fact.¹

In sum, and for the reasons set forth herein, Mederi Caretenders does not concur with any of the recommendations set forth in the Draft Report. Specifically, Mederi Caretenders does not concur with the Report's recommendation that it should refund an estimated \$5,251,925 Medicare overpayment because the forty-two denied claims upon which the overpayment is based were correctly reimbursed by Medicare and there is no refund owed. Further, the statistical sampling that produced the estimated \$5,251,925 overpayment is fundamentally flawed and an unreliable basis for extrapolation. Mederi Caretenders also does not concur with the Report's recommendation that it identify and return "similar overpayments" outside the four-year claim reopening period because it disagrees with the audit finding of any overpayment. Moreover, Mederi Caretenders already has effective policies and procedures in place to identify and return overpayments within sixty days in the ordinary course of business. Finally, Mederi Caretenders does not concur with the Report's recommendation that it strengthen its controls to ensure full compliance with Medicare billing requirements. While it continually assesses and seeks to improve upon its billing and compliance policies and procedures, Mederi Caretenders presently has strong controls in place to ensure full compliance with Medicare billing requirements. The fact that we can show that all of the audited claims met Medicare billing requirements proves this fact.

For these reasons, we respectfully request that OIG take into account our defense of each of the forty-two denied claims and the arguments set forth below, and consider the complete record before issuing its final report.

I. The Independent Medical Review Contractor Incorrectly Concluded that Thirty-Three Patients Were Not Homebound

The independent medical review contractor denied thirty-three claims on the grounds that the patients were not homebound. A review of the complete medical record and the applicable law shows that the independent medical review contractor was wrong in each instance.

A patient need not be bedridden to be considered homebound. Rather, the condition of the patient must be such that leaving home is not recommended because of the beneficiary's condition, the beneficiary requires help (e.g., a wheelchair, walker, special transportation, or accompaniment of another person) to leave home, and leaving home requires a considerable and taxing effort. A patient may be homebound and still leave the home for needed medical treatment

¹ Mederi Caretenders is also enclosing its response to the Internal Control Questionnaire, along with all applicable policies and procedures.

and short, infrequent non-medical reasons. Homebound status must be determined on a case-by-case basis.

Mederi Caretenders is enclosing a detailed argument for each of the thirty-three patients showing that they were in fact homebound under the applicable Medicare regulations and guidance governing homebound status. Examples of the errors committed by the independent medical review contractor in concluding the patient was not homebound are set forth below.

For example, the independent medical review contractor determined that Patient #14 was not homebound because she left the home for outpatient psychiatric treatment. This is a clear error. The Medicare Benefit Policy Manual specifically states that absence from the home to receive health care treatment shall not disqualify an individual from being considered homebound. Medicare Benefit Policy Manual, Chapter 7, § 30.1.1. The independent medical review contractor ignored this clear mandate as well as the voluminous evidence in the patient's medical record demonstrating her homebound status, including the following:

- Patient's use of a wheeled walker due to severe pain, balance issues and shortness of breath with household ambulation. She also needed stand-by assistance of another person.
- Documentation of patient's risk for falls which resulted in a need for supervision to negotiate stairs.
- Back and knee pain assessed as 7 out of 10 with movement and ambulation and a new diagnosis of depression and anxiety.

The independent medical review contractor's mistaken belief that Patient #14 was not homebound because she left the home for medical treatment is belied by ample documentation showing homebound status in the patient's medical record and by the plain language of the Medicare Benefit Policy Manual itself.

The independent medical reviewer also improperly considered short, infrequent trips from home for family visits as disqualifying for Patient #2. Again, this is contrary to the specific guidance set forth in the Medicare Benefit Policy Manual, Chapter 7, § 30.1.1, which allows for short, infrequent trips outside the home and specifically provides the example of family visits. In addition to overlooking the Manual guidance, the contractor also overlooked the ample evidence of homebound status in Patient #2's medical record, including two falls with injuries in the past year, severe pain (10 out of 10), memory loss and confusion issues and difficulty ambulating twenty feet.

In many instances, it is clear the independent medical review contractor did not consider the entire medical record but instead latched on to any single episode in the record showing the patient doing well (often as the result of the high quality skilled care provided by Mederi Caretenders) as evidence the patient was not homebound. For example, the independent medical review contractor concluded that Patient #27 was not homebound because of progress she made in physical therapy and the success Mederi Caretenders had in controlling her pain. This ignores the totality of the medical record, which demonstrates unequivocally that Patient #27 was homebound. Patient #27 was discharged to home health after being hospitalized for a fall with injuries where she had hit her head on concrete. She used a walker and required stand-by assistance, suffered pain, shortness of breath with ambulation of twenty feet, increased thoracic kyphosis, shuffling gait and sensory organization deficits affecting safety and gait. Mederi Caretenders provided physical therapy for fall prevention, and the medical record shows that the care provided resulted in an improvement of the patient's safety and mobility and a significant reduction in her pain from 8 out of 10 to 1 out of 10.

Another example is Patient #41, who the independent medical review contractor concluded was homebound at the start of care but was no longer homebound after twenty-six days of care. Patient #41 was admitted to home health following hospitalization for a hip fracture she suffered after falling in the shower. She also suffered from shoulder pain as a result of the fall. Mederi Caretenders provided physical therapy to improve her strength and mobility. However, the independent medical review contractor wrongly concluded that she was no longer homebound after twenty-six days because of the gains she made in physical therapy to strengthen her hip and lower extremities that allowed her to bear weight by that point. The contractor ignores the fact that Patient #41 was also receiving physical therapy for her shoulder injury, which prevented her from safely using her walker. The medical record, if reviewed in its entirety, clearly documents that the patient remained at high risk for falls due to the pain and weakness in her shoulder, which impacted her mobility because she used a walker.

Patient #46 is yet another example of the independent medical review contractor latching onto any progress in physical therapy as a reason to conclude the patient is not homebound. Here, the contractor relies on a 7/15 physical therapy session where the patient was able to ambulate 100 feet without an assistive device as proof the patient was not homebound. Had the contractor reviewed the entire medical record, the error of this conclusion would have been apparent. The notes from that same 7/15 physical therapy session document that the patient used a handrail with stand-by assistance and verbal cues to ambulate 100 feet, and after doing so, she had extreme dizziness and had to sit down to recover. The therapist also documented on 7/15 that the patient was considered unsafe in the home. On 7/21, after the contractor considered her no longer homebound, the physical therapy notes actually show her mobility had decreased to 60 feet and that she had increased fatigue, pain and dizziness. On 7/30, again after the independent

medical review contractor determined the patient was no longer homebound, she suffered a fall.² Had the contractor reviewed the record beyond the 7/15 therapy notes, or even reviewed the totality of the 7/15 therapy notes, they would have realized the patient remained homebound throughout the entire episode of care.

Finally, the independent medical review contractor erroneously appears to use the fact that a patient lives in an assisted living facility to conclude the patient is not homebound. This is at odds with the Medicare Benefit Policy Manual, which explicitly lists assisted living facilities as residences where patients may reside without disqualifying them from being homebound, provided that the skilled services offered by the home health agency are not also offered at the assisted living facility. Medicare Benefit Policy Manual, Chapter 7, § 30.1.2.A. Patient #42 provides an example of a patient living in an assisted living facility who the independent medical review contractor improperly concluded was not homebound because of that fact. The medical records show that Patient #42 suffered from psychiatric issues, anorexia, memory loss, anxiety and impaired cognition,³ all of which impacted on her ability to safely leave the home, which in her case, was an assisted living facility. The patient used a cane and required stand-by assistance, was dyspneic after 20 feet, and had poor balance and a shuffling gait. Importantly, the skilled services she required, including physical therapy, were not offered at the assisted living facility. Therefore, the independent medical review contractor erred in determining that her residence at an assisted living facility meant that she was not homebound.

II. The Independent Medical Review Contractor Incorrectly Concluded that Seventeen Patients Did Not Need Skilled Nursing or Therapy

The independent medical review contractor denied seventeen claims on the basis that the patient did not need skilled nursing or therapy. Again, the error in these conclusions seems to stem from the independent medical review contractor's failure to consider the entirety of the patient's medical record.

The Medicare home health benefit covers skilled nursing care, physical therapy, occupational therapy, and speech-language pathology services, medical social services, and medical supplies that are reasonable and necessary for the treatment of the patient's illness or injury. Skilled nursing can be performed by a registered nurse or a licensed vocational/practice

² Patient #49 is yet another instance of the medical record showing that the patient suffered a fall after the date that the independent medical review contractor determined the patient was no longer homebound. Like Patient #46, the independent medical review contractor used the fact that the patient ambulated 130 feet without an assistive device at a 3/25 physical therapy session to conclude she was no longer homebound after that date, while ignoring the 3/25 physical therapy notes which clearly document the patient was "staggering," had to grab onto furniture to steady herself and suffered shortness of breath. The medical records show she suffered a fall on 4/10.

³ The Medicare Benefit Policy Manual explicitly provides the example of psychiatric conditions such as this as impacting the patient's ability to safely leave the home. Medicare Benefit Policy Manual, Chapter 7, 30.1.1.

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nurse under a registered nurse's supervision. Home health nurses provide direct care (e.g., injections, changing dressings) and also instruct patients and their caregivers about appropriate care (e.g., for diabetes management). Physical and occupational therapy is covered when it is a safe and effective treatment for a beneficiary's condition and can only be provided by qualified therapists and it is expected that the condition for which therapy is ordered will improve over time or therapy is necessary to establish or perform an effective maintenance program. Additionally, home health aide services are covered when given on a part-time or intermittent basis to support skilled nursing care or therapy.

Patient #17 provides a good example of the independent medical review contractor determining there was no skilled need without carefully considering the patient's entire medical record. The conclusion of no skilled need appears to be based primarily on the fact that the nurses taught wound care to the patient's caregiver and the caregiver said she understood. However, the independent medical review contractor ignores the patient's complicated medical history and the full record, both of which amply demonstrate a skilled need. Patient #17 had recent sepsis, recent urinary tract infection, an unstable pressure ulcer on the sacrum, seizures, hypertension, and a suprapubic catheter. The skilled nursing visits that Mederi Caretenders provided resulted in new medications being prescribed because the skilled nurses noticed the patient's changing condition. The skilled nurses were also critical to assess the healing of complicated wounds, despite the fact that the records show the caregiver verbally responded that she understood the limited wound care that she was taught. Skilled nursing was further required for teaching on the suprapubic catheter and on the new phenobarbital prescription.

In other instances, the independent medical review contractor determines skilled therapy is no longer necessary after a certain date because the patient had reached his or her functional plateau. In each instance, the error in the contractor's conclusion is apparent in the medical records, which show the patients making continuing progress after the date on which the independent medical review contractor assumed they had reached their functional plateau. For example, the independent medical review contractor wrongly concludes that Patient #57 reached her functional plateau on 11/4. This is belied by the fact that the medical records show Patient #57 making continuing progress in physical therapy after 11/4.⁴ The independent medical review contractor also incorrectly assumes that the skilled need for physical therapy was only for

⁴ Patient #78 provides another good example of a patient who showed continuing progress with physical therapy, after the date on which the independent medical review contractor incorrectly concluded the patient had reached her functional plateau.

walking, when the medical records clearly show the physical therapy was also aimed at improving the patient's safety with ambulation, transferring and fall prevention.

Patient #60 provides yet another example of the independent medical review contractor not reviewing the entirety of the medical record before determining the patient no longer had a skilled need after a certain date. In this instance, the contractor concluded the patient no longer needed physical therapy after 5/26. The medical records show the patient suffered a fall with injuries on 6/18, which is proof of her continuing need for physical therapy to improve safety and strengthening. In addition, Patient #60's physical therapy notes show continuing progress in physical therapy after 5/26.

III. The Independent Medical Review Contractor Incorrectly Determined that Five Claims Were Incorrectly Coded

The independent medical review contractor's conclusions with regard to coding also do not hold up to scrutiny. For example, the contractor determines that claims for Patient #51 are incorrectly coded. However, it is the independent medical review contractor who is incorrect. The contractor overlooks a new Grouper that CMS implemented on October 1, 2015. Mederi Caretenders correctly coded the claim according to the new CMS Grouper. In another instance for Patient #85, the independent medical review contractor uses a minor clerical error in which a single data field in the OASIS form is inadvertently skipped to deny a claim for supposed lack of medical necessity. However, the independent medical review contractor also concludes for that same patient that the physical and occupational therapy that Mederi Caretenders provided was medically necessary. The inconsistency in these conclusions shows that this is at most a minor clerical error which should not be used as a basis for denying the patient's claim.

IV. The Independent Medical Review Contractor Incorrectly Denied One Claim for Missing Documentation

From the 100 claim sample, there was only a single claim that was found to lack sufficient documentation. Specifically with regard to Patient #81, Mederi Caretenders was unable to locate the Face to Face documentation. However, this single oversight should not be used as the basis for denying the claim. First, the independent medical review contractor concluded that Patient #81 was homebound and did require skilled services. Second, there is ample documentation in the record showing that a face to face encounter with the patient's physician occurred in the prescribed time period. Specifically, the records show that Patient #81 was seen by the certifying physician on 9/24 in a face to face encounter and was referred to home

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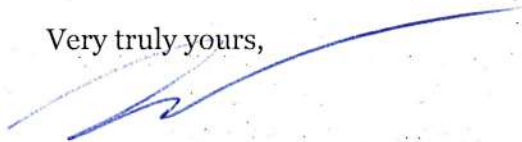
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care on 9/26. The records further document communications between the certifying physician and the physical therapist. Following the Start of Care assessment, the physical therapist notified the physician of his findings and obtained orders, including a home exercise program, safety training, interventions to relieve pain including infra-red treatments, transfer and gait training. During the episode, the notes support the therapist was monitoring the patient's edema. On 11/14 the patient stated he was reluctant to take the new medicine prescribed by the cardiologist, Furosemide. The therapist encouraged the patient to take all his medicine as prescribed and notified the physician. In sum, the care provided was medically necessary and skilled, and the patient's functional ability improved. The records support there was communication between the therapist and the physician at the Start of Care and at Recertification to notify the physician of the assessments and obtain orders. Also the therapist contacted the physician on 11/14 in regards to the patient's treatment/prescribed medicine. The single discrepancy involving a missing face to face form should not be used to deny payment for the quality skilled care Patient #81 received, which led to an improvement in his functional ability.

In closing, Mederi Caretenders respectfully requests that OIG take a second look at the findings of the independent medical review contractor in light of the information provided in this response. Mederi Caretenders continues to welcome any opportunity to meet with your office and the independent medical review contractor to work through these issues so that the final report issued by OIG is as fair and accurate as possible. We are enclosing the forty-two individual patient responses, the report of our expert on the statistical sampling/extrapolation and our answers to the Internal Control Questionnaire, along with the policies and procedures referenced therein. If there is anything else that we can provide, please do not hesitate to ask.

Very truly yours,



Jennifer L. Weaver

Enclosures

JLW:cwb