

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY
PROVIDER COMPLIANCE REVIEW:
ANGELS CARE HOME HEALTH**

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Office of Inspector General

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Report in Brief

Date: October 2019

Report No. A-07-16-05093

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 Angels Care Home Health (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 (28 of which 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 submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

Medicare Home Health Agency Provider Compliance Review: Angels Care Home Health

What OIG Found

The Agency did not comply with Medicare billing requirements for 29 of the 72 home health claims paid in CYs 2014 or 2015 that we reviewed. For these claims, the Agency received overpayments of \$57,148. Specifically, the Agency incorrectly billed Medicare because (1) beneficiaries were not homebound, (2) beneficiaries did not require skilled services, or (3) claims were assigned with incorrect Health Insurance Prospective Payment System payment codes. On the basis of our sample results, we estimated that during CYs 2014 and 2015 the Agency received overpayments totaling \$3.8 million.

What OIG Recommends and Agency Comments

We recommended that the Agency (1) refund to the Medicare program the portion of the \$3.8 million in estimated overpayments received during CYs 2014 and 2015 for claims incorrectly billed and within the reopening and recovery periods; (2) for the rest of the \$3.8 million in estimated overpayments for claims that are outside the 4-year reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; (3) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and (4) strengthen controls to ensure full compliance with requirements for billing home health services.

The Agency disagreed with most of our findings and did not concur with any of our recommendations, including our extrapolated overpayment. The Agency disagreed with the determinations for 25 of the 41 claims questioned in our draft report, and it provided additional documentation related to these claims. The Agency agreed that 16 of the reported claims were not billed correctly. The Agency said that our draft report significantly overstated the error rate and that our statistical sampling methodology was unreliable and inherently flawed. After reviewing the Agency's comments, its additional documentation, and the results of additional medical review, we revised our determinations, reducing the total number of reportable error claims from 41 to 29, and revised our related findings and recommendations. We maintain that all of our findings, as revised, and all of our recommendations remain valid. Our medical review contractor considered the entire medical record associated with each of the claims in question, and made its determinations in accordance with Medicare guidelines. Our statistical approach resulted in a legally valid and reasonably conservative estimate of Medicare's overpayments to the Agency.

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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 Angels Care Home Health (the Agency) complied with Medicare requirements for billing home health services provided in CYs 2013, 2014, or 2015.¹

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)

¹ The name of the entity is Custom Care of Ellsworth, Inc., but during our audit period it did business as Angels Care Home Health.

payment codes² and represent specific sets of patient characteristics.³ CMS requires HHAs to submit OASIS data as a condition of payment.⁴

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 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

² 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.

³ 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.

⁴ 42 CFR §§ 484.20, 484.55, 484.210(e), and 484.250(a)(1); 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).⁵

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

Angels Care Home Health

The Agency is a home health care agency located in Salina, Kansas. CGS Administrators, LLC (CGS), its Medicare contractor, paid the Agency approximately \$21 million for 10,178 claims for services provided in CYs 2013, 2014, or 2015 (audit period) on the basis of CMS’s National Claims History (NCH) data.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$20,287,182 in Medicare payments to the Agency for 8,914 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 \$265,960 for review (28 of these claims were for services paid in CY 2013 that were outside of the 4-year claim-reopening period at the

⁵ 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).

time we issued our draft report to the Agency).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 29 of the 72 home health claims paid in CYs 2014 or 2015 that we reviewed.^{8,9} For these claims, the Agency received overpayments of \$57,148 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, or
- claims contained incorrect HIPPS billing codes.

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

⁶ 42 CFR § 405.980(b)(2).

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

⁸ We identified eight other home health claims 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 12 of the 28 home health claims for home health services provided in CY 2013 that we reviewed.

On the basis of our sample results, we estimated that during CYs 2014 and 2015 the Agency received overpayments totaling at least \$3,808,603.¹⁰ 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 29 of the 72 sampled claims for services paid in CYs 2014 or 2015 that we reviewed, which resulted in overpayments of \$57,148. (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.

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

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.

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

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.

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

¹² Of these 15 claims with homebound errors, 3 claims were also billed with skilled services that were not medically necessary and 1 claim was also billed with an incorrect billing code. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

Example 1: Beneficiary Not Homebound – Entire Episode

Documentation for one beneficiary did not support that the patient was homebound, because at the start of care, the patient was walking frequently and had no mobility limitations. 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 1395n(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).

For 16 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, skilled services were ordered solely for education about the disease process and the management of atrial fibrillation and anticoagulant usage and the patient had already received them. The patient's condition was unchanged and there were no recent hospitalizations or falls. Therefore, skilled nursing care was not reasonable and necessary.

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).

¹⁴ Of these 16 claims with skilled need service that were not medically necessary, the Agency billed 3 of the claims for beneficiaries with homebound errors. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

Incorrectly Billed Health Insurance Prospective Payment System Billing Codes

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 two of the sampled claims, our medical reviewer determined that the Agency billed Medicare with incorrectly coded claims that resulted in higher HHA claim payments to the Agency. Specifically, certain HIPPS codes were not supported in the medical records.¹⁵

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 \$3,808,603.

RECOMMENDATIONS

We recommend that the Agency:

- refund to the Medicare program the portion of the \$3,808,603 in estimated overpayments received during CYs 2014 and 2015 for claims incorrectly billed that are within the reopening and recovery periods;¹⁶
- for the remaining portion of the \$3,808,603 in estimated overpayments for claims that are outside the 4-year reopening period, exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;

¹⁵ Of these two incorrectly coded claims, the Agency billed one of the claims for a beneficiary with a homebound error. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

¹⁶ 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.

- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit 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 most of our findings and did not concur with any of our recommendations, including our extrapolated overpayment. Specifically, the Agency disagreed with the determinations for 25 of the 41 claims questioned in our draft report, and it subsequently provided additional documentation related to these claims. The Agency agreed that 16 of the reported claims were not billed correctly. The Agency said that our draft report significantly overstated the error rate and that the statistical sampling methodology that we used was unreliable and inherently flawed. The Agency added that our independent medical review contractor “may have made certain improper assumptions in determining homebound status and medical necessity.”

The Agency separately provided additional documentation related to the claims that our draft report had questioned and enclosed the results of its consultant’s review of the 41 claims questioned in our draft report.

To address the Agency’s concerns, we requested that our independent medical review contractor review the Agency’s written comments on our draft report, the supplemental documentation and consultant’s report that it provided.¹⁷

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 41 to 29, 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, appear as Appendix F. We are providing the Agency’s comments in their entirety to CMS.

¹⁷ The Agency’s comments and consultant’s report were limited to the 41 claims for services paid in CYs 2014 and 2015 which we determined were paid in error. Accordingly, we did not submit the 12 claims for services provided in CY 2013 that we determined were paid in error to our independent medical review contractor for further review. See footnote 9.

BENEFICIARIES WHO WERE NOT HOMEBOUND

Auditee Comments

The Agency disagreed with most of our findings related to homebound status, stating that its consultant had determined that 19 of the 30 claims conveyed in our draft report contained fully compliant documentation to support homebound status. The Agency referred to instances in which our medical reviewer concluded that the patient did not meet homebound status. In these cases, the Agency's consultant concluded that our medical reviewer had focused on only one aspect of homebound status, "such as the distance the beneficiary was able to ambulate or a single instance of an absence from the home," while ignoring the context of the patient's overall condition.

The Agency cited the two criteria conveyed in the Manual and pointed to an example of a claim that we had questioned but which involved a beneficiary ("Beneficiary 9") who was, according to the Agency, homebound under applicable Medicare regulations and guidance, to include the Manual. For this beneficiary, the Agency described various cognitive issues, stating that "the beneficiary understands only basic conversation or simple phrases; that she needs prompting; that she has errors in word choice, organization, and speech intelligence; that she loses track of her thoughts and gets frustrated; that she is frequently confused; that she had forgotten a recent prior visit; that she forgets to change her clothes; and that she is generally forgetful during tasks, requiring reminders."

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 30, involved beneficiaries who did not meet the criteria for being homebound.

We disagree with the Agency's assertion that our medical reviewer had focused on only one aspect of homebound status and ignored the context of the patient's overall condition. 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.

The Agency also pointed to "a single instance of an absence from home" as another example of what it referred to as our medical reviewer's focus on "single items in the medical record." 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.

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.

With respect to Beneficiary 9, the example that the Agency cited of the beneficiary who had cognitive issues, 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 focusing on only one aspect of homebound status while ignoring the context of the beneficiaries' overall condition as conveyed in their medical records, the medical review contractor examined all 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 Beneficiary 9, the most recent determination by our independent medical review contractor noted, "Although she had dementia, the patient resided with her spouse and had caregiver assistance available. Leaving the home would not require a considerable or taxing effort."

Accordingly, having revised our findings and the associated recommendation with respect to 15 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 most of our findings related to skilled services, stating that its consultant determined that 13 of the 24 claims conveyed in our draft report had fully documented the medical necessity of skilled nursing or therapy services. The Agency stated that, in the records associated with several of the sampled claims, our medical reviewer had disregarded the Manual's guidance regarding the fact that occupational therapy and physical therapy are distinct disciplines that address different needs. According to the Agency, its consultant identified a number of cases in which the beneficiaries had received occupational therapy services that were unique and not addressed by the beneficiaries' physical therapists.

The Agency also stated that, in several instances, our medical reviewer had disregarded guidance related to the medical necessity of home health skilled nursing. The Agency cited an example of a claim related to one beneficiary ("Beneficiary 22") for which we had questioned the medical necessity of skilled nursing services. Regarding this beneficiary, who had received a primary diagnosis of type II diabetes and a number of secondary diagnoses, the Agency stated: "Based on the need to alter the plan of care throughout this episode due to the beneficiary's significant diagnoses and comorbidities, the episode meets Medicare coverage criteria for skilled observation and assessment as well as teaching and training."

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 16 claims, rather than

24, 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 disregarding the Manual's guidance regarding the distinct disciplines of physical and occupational therapy, or the guidance related to the medical necessity of home health skilled nursing, 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 Beneficiary 22, the example that the Agency cited of the beneficiary who had received home health skilled nursing services for management of the disease process of diabetes, our independent medical review contractor determined that "[t]he patient's conditions were stable and there was no history of recent injury. There was no history of significant cognitive impairment which would impede his processing of the prior educational material related to his medical condition. Moreover, he was noted to be compliant with monitoring of his diabetic status and medications."

Accordingly, having revised our findings and the associated recommendation with respect to 8 of the claims identified in our draft report, we maintain that our findings for the remaining 16 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 six of the findings for billing code errors that our draft report had conveyed. The Agency said that its consultant calculated the payments and determined that each claim was billed correctly. The Agency cited an example of a claim (related to “Beneficiary 51”) that we had questioned but which involved a billing code that was, according to the Agency, correct.

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 two claims, rather than six, involved incorrectly billed HIPPS codes. The medical review contractor examined all 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. With respect to Beneficiary 51, for example, our independent medical review contractor determined the correct billing code to be different from the code that the Agency’s consultant stated was the correct one.

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

CLAIMS WITH MISSING DOCUMENTATION

Auditee Comments

The Agency disagreed with one of the two claims that, our draft report stated, lacked adequate documentation. The Agency said that one of the claims had adequate documentation but agreed that the other claim did not.

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 removed our finding related to missing documentation (and the associated recommended disallowance) from this final report.

The medical review contractor examined all 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.

Although the Agency agreed that one of the claims in question lacked adequate documentation, our independent medical review contractor's additional review of the medical records and the separately submitted documentation concluded that both of the claims in question were adequately documented. Accordingly, we removed the finding on what the Agency's comments referred to as "Documentation Issues" from this final report.

USE OF STATISTICAL SAMPLING

Auditee Comments

The Agency stated that our statistical sampling methodology was unreliable and inherently flawed, thereby calling into question the statistical validity of the extrapolated overpayment. The Agency said that our sample size of 100 claims represented 1.12 percent of the universe of claims for our audit period and added that "[b]ecause of this small sample size, the OIG's extrapolation does not have the statistical integrity required" by Medicare requirements and industry standards. In addition, the Agency said that our universe or sampling frame suffered from an "inherent bias" because it did not include lower-paid claims of \$1,000 or less, which, the Agency said, "inflated arbitrarily the dollar amounts at issue in the universe."

Furthermore, the Agency stated that neither the sampling frame nor the statistical sample should have included claims from CY 2013, which lay outside the 4-year reopening period. In this context, the Agency said that our draft report was not clear as to whether the CY 2013 claims in question were for services provided in CY 2013 or for claims paid in CY 2013. Finally, the Agency referred to AdvanceMed's nonstatistical reviews (Appendix D) and acknowledged that we subtracted \$63,156 from the estimated extrapolated overpayment, but "[a]t no time did the OIG remove the claims separately reviewed by AdvanceMed from the universe of claims reviewed by the OIG, which would have been the proper approach."

The Agency concluded its discussion of our statistical methodology by saying that it "objects to the extrapolated overpayment and any recoupment of its reimbursement based on such a tenuous statistical sampling methodology."

Office of Inspector General Response

We carefully considered the Agency's comments on 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. 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 confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

Several of the specific comments that the Agency made to support its characterization of our statistical sampling methodology as "tenuous" drew upon an incorrect or incomplete understanding of that methodology. Contrary to the Agency's description of an "inherent bias" in our sampling frame, our statistical estimate did not extend beyond the frame from which the sample was selected. Because the frame did not include claims of less than \$1,000 dollars, our recommended recovery applies only to claims greater than \$1,000 dollars. As a result, excluding payments less than \$1,000 dollars reduces, rather than inflates, the estimated overpayment amount.

Concerning the Agency's comments about claims from CY 2013, any demand for repayment that is made upon the Agency will be restricted to a valid and conservative estimate of overpayments for claims that are in the sampling frame and within the reopening period. To clarify this point, we have revised, for this final report, both the description of our sampling methodology (in "How We Conducted This Review" and Appendix A) and our findings and first recommendation.

Regarding the Agency's stated uncertainty about the CY 2013 claims, we used year of payment, not date of service, to segregate claims for the overpayment calculation and projection. A claim with dates of service in CY 2013 can be paid in CY 2014. CMS regulations provide that Medicare contractors may reopen payment determinations, but the clock for reopening begins to run from the date the claim was paid.

With respect to the Agency's comments on the \$63,156 that we subtracted from the estimated extrapolated overpayment to account for AdvanceMed's reviews, we calculated a conservative estimate of the total overpayment amount in the sampling frame and then adjusted this conservative lower limit by subtracting out the known amount previously identified by AdvanceMed. Given that the total overpayment amount is conservative, and the amount identified by AdvanceMed is known, the resulting total is also conservative. In fact, our approach is more conservative, on average, than the approach that the Agency suggested was the "proper" one.

AUDITEE COMMENTS ON OFFICE OF INSPECTOR GENERAL RECOMMENDATIONS

Auditee Comments

The Agency did not concur with our first recommendation but agreed to refund amounts consistent with the 16 claims "for which the documentation was insufficient to support the claim as paid."

Regarding our second recommendation, the Agency stated that it takes seriously its compliance with the 60-day rule but does not concur that its obligations under that rule are triggered by our report. The Agency cited its consultant's determination that only 16 of the claims in our findings had problems, and added that "[d]eterminations of medical necessity and homebound status are necessarily subjective, and identifying issues with only nine claims in each of these categories is not indicative of a widespread pattern or practice of improper claims submission." The Agency also referred to the fact that CMS, the cognizant U.S. Department of Health and Human Services operating division, makes final determinations on OIG audit recommendations, and to the fact that providers have the right to appeal those determinations.

The Agency did not concur with our third recommendation. Citing its consultant's determinations about the claims in our findings, the Agency echoed its statement earlier in its

written comments that “this low error rate is not indicative of a system-wide lack of controls” at the Agency.¹⁸

Office of Inspector General Response

Independent medical review contractors examined all of the medical records and documentation submitted by the Agency and carefully considered this information to determine whether the Agency billed the claims in compliance with selected billing requirements and to thereby conclude whether the services met coverage, medical necessity, and coding rules. Furthermore, in response to the Agency’s concerns regarding our determinations for the 41 home health claims questioned in our draft report, we initiated additional medical review. Based on the results of this review, we revised our determinations, reducing the total number of sampled claims in error from 41 to 29, 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. Our responses to the Agency’s comments on our recommendations follow.

Under the 60-day rule, providers who receive overpayments are required to return them within 60 days after the date on which the overpayments were identified (section 1128J(d) of the Act and 42 CFR §§ 401.305(a) and (b)). In addition, providers that receive credible information of overpayments must exercise reasonable diligence to determine whether they have received an overpayment and to quantify the amount of the overpayment (42 CFR § 401.305(a)(2) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)). In exercising reasonable diligence, providers are expected to determine whether overpayments exist during a 6-year lookback period (42 CFR § 401.305(f)). In addition, the provider may quantify the entire amount of the overpayment for this lookback period using a statistically valid extrapolation methodology (42 CFR § 401.305(d)(1)).

The OIG believes that this audit report constitutes credible information of potential overpayments. As a result, the Agency has a duty to exercise reasonable diligence to determine whether the Agency has received an overpayment and to quantify the amount of the overpayment. Our audit period is CYs 2013, 2014 and 2015, which leaves CYs 2016 to the present as unaudited and within the 6-year lookback period required by the 60-day rule. Accordingly, we are recommending that the Agency exercise reasonable diligence to determine whether it received overpayments during the entire 6-year lookback period. The Agency is correct, of course, that CMS makes final determinations on OIG audit recommendations and providers have the right to appeal those determinations. The Medicare Part A/B appeals process has five levels and, if a provider exercises its right to an appeal, it does not need to return overpayments until after the second level of appeal.

¹⁸ This passage in the Agency’s comments includes a footnote that refers to our determination that the Agency did not have adequate controls to prevent the incorrect billing of Medicare claims. “Nowhere does the Draft Report cite to support for this statement or describe how the OIG came to believe this was true.”

Our revised finding, that 29 of the 100 sampled claims were in error, continues to argue for the Agency's need to strengthen its controls to ensure full compliance with Medicare requirements for billing home health services. In response to the Agency's assertion that we did not provide support or evidence for our statement that the Agency lacked adequate controls, we posit that our findings themselves constitute the support for that statement because the findings demonstrate that the agency did not have adequate controls in place to prevent the incorrect billing of Medicare claims. We continue to maintain, therefore, that our third recommendation is valid.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$20,287,182 in Medicare payments to the Agency for 8,914 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 the 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 18 home health claims for services paid in CY 2013 that we reviewed and that were potentially outside of the 4-year claim-reopening period. We selected for review a stratified random sample of 100 home health claims with payments totaling \$265,960.

We evaluated compliance with selected billing requirements and submitted claims to focused medical review to determine whether the services met coverage, 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 June 2016 through November 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 \$265,960 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 100 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 28 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 April 20, 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 rate 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, 484.210(e), and 484.250(a)(1); 74 Federal Register 58077, 58110—58111 (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;¹⁹ (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).

¹⁹ 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.

The Act and Federal regulations state that Medicare pays for home health services only if a physician certifies that the beneficiary meets the above coverage requirements (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and 42 CFR § 424.22(a)).

Section 6407(a) of the Affordable Care Act²⁰ 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.²¹

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

²⁰ 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.

²¹ 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.²²

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.

²² 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 8,914 home health claims, valued at \$20,287,182, from CMS's NCH file.²³

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	\$1,027.98 to \$1,894.02	4,401	34	\$7,093,191.26
2	\$1,894.03 to \$3,080.38	2,987	33	6,732,526.73
3	\$3,080.39 and higher	1,526	33	6,461,464.45
	Totals	8,914	100	\$20,287,182.44

SAMPLE SIZE

We randomly selected 34 unique home health 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.

²³ 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) three 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 4,401 for stratum 1; from 1 to 2,987 for stratum 2; and from 1 to 1,526 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 Items²⁴	Value of Overpayments In Sample
1	17	\$25,554
2	5	9,016
3	7	22,578
Total	29	\$57,148

ESTIMATES

**Estimate of Overpayments for the Audit Period²⁵
(Limits Calculated for a 90-Percent Confidence Interval)**

	OIG, OAS, Statistical Software Estimate	Less: AdvanceMed Corporation Finding	Report Estimate
Point Estimate	\$5,167,891	\$63,156	\$5,104,735
Lower Limit	\$3,871,759	\$63,156	\$3,808,603
Upper Limit	\$6,464,023	\$63,156	\$6,400,867

²⁴ We identified eight 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 eight claims because they had no effect on overpayments.

²⁵ AdvanceMed Corporation performed separate nonstatistical reviews of the Agency. The AdvanceMed reviews included \$63,156 in unallowable payments during the time period that is within the Medicare reopening and recovery period that overlapped with our sample frame. To account for these payments, we subtracted \$63,156 from our estimate.

APPENDIX E: TYPES OF ERRORS, BY SAMPLE ITEM, FOR 2014 AND 2015

STRATUM 1

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment
1		X			\$1,231.56
2					-
3					-
4		X			1,477.39
5		X			1,157.40
6					-
7					-
8	X				1,489.12
9	X				1,529.60
10		X			1,531.32
11					-
12					-
13					-
14		X			1,531.32
15					-
16					-
17					-
18		X			1,574.50
19		X			1,394.00
20					-
21		X			1,251.08
22		X			1,617.50
23	X	X			1,617.50
24	X				1,617.50
25	X				1,652.08
26		X			1,652.08
27					-
28		X			1,447.37
29					-
30					-
31					-
32		X			1,782.57
33					-
34					-

STRATUM 2

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment
35					-
36					-
37					-
38	X				1,922.44
39	X	X			1,937.99
40					-
41					-
42					-
43					-
44					-
45					-
46					-
47					-
48					-
49					-
50					-
51			X		2,103.12
52					-
53					-
54					-
55	X				2,206.00
56					-
57					-
58					-
59					-
60					-
61					-
62					-
63					-
64	X				846.60
65					-
66					-
67					-

STRATUM 3

Sample	Not Homebound	Did Not Require Skilled Services	Incorrectly Billed HIPPS Code	Missing or Insufficient Documentation	Overpayment
68					-
69					-
70					-
71					-
72					-
73					-
74					-
75					-
76					-
77	X				\$776.43
78					-
79					-
80					-
81	X		X		3,717.93
82					-
83					-
84					-
85	X				2,445.89
86					-
87					-
88					-
89	X				4,374.26
90					-
91					-
92					-
93	X				4,618.41
94		X			1,557.04
95					-
96					-
97	X	X			5,088.16
98					-
99					-
100					-
Totals	15	16	2	0	\$57,148

APPENDIX F: AUDITEE COMMENTS

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February 20, 2018

Via FedEx and E-mail

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

Re: *Angels Care Home Health*
Updated Comments to OIG Draft Report No: A-07-16-05093

Dear Mr. Cogley:

This letter is in response to your letter dated November 21, 2017, which enclosed a U.S. Department of Health and Human Services, Office of Inspector General (“OIG”) draft report titled *Angels Care Home Health Billed for Home Health Services That Did Not Comply With Medicare Billing Requirements* (the “Draft Report”). Your letter requested that Angels Care Home Health (“Angels Care” or the “Agency”) provide written comments to the Draft Report within 30 days, a deadline that was subsequently extended to January 15, 2018. On January 12, 2018, we submitted comments to the Draft Report in the form of a letter and expert reports.¹ Through an email received from Scott Englund of your office on January 19, 2018, we learned that there had been confusion about the patients at issue in the OIG’s review. See January 19, 2018 Email from Scott Englund attached as **Exhibit B**. Following additional communications with Mr. Englund, we confirmed the universe of patients at issue and now submit updated comments to the Draft Report in the form of this letter and accompanying materials.

As discussed more fully below, Angels Care disagrees with the findings, recommendations, and alleged extrapolated overpayment set forth in the Draft Report and separate document of claim-specific findings. To assist in its review, Angels Care engaged Simone Healthcare Consultants (“Simione”), a leading consulting firm specializing in home health and hospice improvement, to conduct an independent review of the forty-one (41) claims deemed by the OIG

¹ Angels Care retained the law firm of Jones Day to represent it in this matter. A copy of email communication with your office memorializing this fact is attached hereto as **Exhibit A**.

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reviewer to not meet Medicare criteria.² Of those forty-one claims, Simione found that all but sixteen (16) fully complied with Medicare billing criteria and were properly paid and that two (2) of those sixteen claims should have been partially paid. *See* Simione Findings, attached hereto as **Exhibit C**. Due to this markedly lower error rate, in combination with concerns about the statistical sampling methodology used, Angels Care disputes the alleged overpayment and the OIG's recommendations, and respectfully requests that the Draft Report be withdrawn.

I. RESPONSE TO THE DRAFT REPORT'S FINDINGS

1. The Draft Report Significantly Overstates the Error Rate.

Simione's detailed findings show that all but sixteen of the claims included in the OIG's sample fully met Medicare documentation and billing requirements and that in two of those sixteen claims partial payment was proper. Contrary to the Draft Report's findings, this low error rate is not indicative of a system-wide lack of controls at Angels Care.³ At best, the discrepancy between the error rate cited in the Draft Report and the error rate found by Simione is a function of the subjective nature of determinations of medical necessity and homebound status. There are also trends among the OIG reviewer's findings which suggest that the reviewer may have made certain improper assumptions in determining homebound status and medical necessity.

A. Homebound Status

The Draft Report states that the OIG's medical reviewer determined that twenty-eight (28) of the sampled claims were incorrectly billed to Medicare because the beneficiary did not meet homebound criteria.⁴ Simione's detailed review shows that nineteen (19) of these claims contained

² The Draft Report states that forty-one (41) of the claims reviewed did not comply with Medicare billing requirements. *See* Draft Report in Brief; Draft Report at 4, 5, 17. The Draft Report also states that the OIG "identified four other home health claims that did not comply with Medicare billing requirements" but said that the OIG was "not reporting on those claims because they had no effect on overpayments." Draft Report at 4 n.7. Simione conducted a review of only the forty-one claims which the OIG determined resulted in an overpayment.

³ The Draft Report states that the errors it identified in its claims review "occurred primarily because the Agency did not have adequate controls to prevent the incorrect billing of Medicare claims." Draft Report at 4. Nowhere does the Draft Report cite to support for this statement or describe how the OIG came to believe this was true. Indeed, it does not appear that the OIG had any basis beyond the alleged error rate itself to make this claim because, as described in the Methodology section of the Draft Report, the OIG reviewed only medical records and claims and billing data. *See* Draft Report at 8-9. Angels Care has considerable controls in place to prevent the incorrect billing of Medicare claims, which is further supported by the significantly lower error rate calculated by Simione.

⁴ The Draft Report cites this number as thirty (30) claims, *see* Draft Report at 5, but this figure appears to include two claims that did not result in an overpayment, in contravention of the Draft Report's statement that the OIG was "not reporting on" claims that did not result in an overpayment, Draft Report at 4 n.7. As discussed above, Simione reviewed only the forty-one claims that the OIG determined resulted in an overpayment.

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fully compliant documentation to support homebound status, however. Notably, in each of the instances in which the OIG reviewer concluded that the patient did not meet homebound status, Simone found that the reviewer had focused on only one aspect of homebound status while ignoring the context of the patient's overall condition.

The Medicare Benefit Policy Manual states that an individual shall be considered "confined to the home" if two criteria are met. First, the patient must either need, "[b]ecause of illness or injury, 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." Second, "there must exist a normal inability to leave home and leaving home must require a considerable and taxing effort." Medicare Benefit Policy Manual, Chp. 7, Sec. 30.1.1. The Manual also states that "longitudinal clinical information about the patient's health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort." *Id.* This clinical information can "include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc." *Id.* Finally, the Manual states that "[i]f 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 relatively short duration, or are attributable to the need to receive health care treatment." *Id.*

Contrary to the Medicare Benefit Policy Manual's guidance, the OIG reviewer frequently focused on single items in the medical record, such as the distance the beneficiary was able to ambulate or a single instance of an absence from the home, without looking at the full clinical picture.⁵ Although detailed summaries of Simone's findings can be found in the attached reports, an example may be instructive.⁶

Beneficiary #9: The beneficiary is an 81-year-old who was recertified with a primary diagnosis of dementia and secondary diagnoses of osteoporosis, coronary artery disease, and a history of falls. She lives in her own home with her spouse who provides assistance with all activities of daily living ("ADLs"). The start of care comprehensive assessment cites significant evidence of cognitive issues, including that the beneficiary understands only basic conversation or simple phrases; that she needs prompting; that she has errors in word choice, organization, and speech intelligence; that she loses track of her thoughts and gets frustrated; that she is frequently confused; that she had forgotten a recent prior visit;

⁵ We understand that your office is in possession of the medical records for each of the patients at issue.

⁶ The Draft Report includes an example of a beneficiary who was found not to be homebound but does not provide either identifying information or sufficient detail for Angels Care to conclusively determine to which beneficiary it refers.

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that she forgets to change her clothes; and that she is generally forgetful during tasks, requiring reminders.

The recertification comprehensive assessment documents an increased need for assistance since admission, noting that the beneficiary requires assistance with dressing, bathing transferring, toileting, and ambulation. The recertification documentation also shows that the beneficiary experiences shortness of breath with moderate exercise and requires use of a cane. Additional notes throughout the episode document the beneficiary as forgetful, needing reminders for all ADLs, forgetting to take medications even when prepared in a medicine box, and requiring assistance of another person due to forgetfulness. It was further noted that the beneficiary required assistance of another to safely leave home due to her cognition, that she leaves home only for medical appointments, that she was experiencing weakness, and that she was considered a fall risk. The comprehensive assessment on 9/17/15 documents that the beneficiary has balance issues, needs direction due to forgetfulness, experiences dizziness at times, and has impaired balance.

The OIG reviewer determined that the beneficiary was not homebound because she had caregiver assistance and because she ambulated to the door without her cane. These findings do not negate the copious evidence in the record that it would be unsafe for the beneficiary to leave home without the assistance of another and use of a cane due to her physical limitations and significant cognitive impairments, and there is no evidence in the medical record that she does leave home for anything other than medical appointments. The patient is thus properly considered homebound.

This example, and the many others discussed in the enclosed Simone reports, suggests that the OIG reviewer failed to consider all clinical information about patients' health status, significantly undercutting the reviewer's findings related to alleged failure to meet homebound criteria.

B. Medical Necessity of Skilled Services

The Draft Report states that the OIG's medical reviewer determined that twenty-two (22)⁷ of the sampled claims were incorrectly billed to Medicare because the beneficiary did not require skilled nursing or therapy services. However, Simone's independent review shows that thirteen (13) of those claims fully documented medical necessity. Once again, there are trends in the OIG reviewer's findings that suggest improper assumptions about the services provided.

⁷ Again, the Draft Report lists this number as twenty-four (24), but this figure appears to include two claims for which no overpayment was calculated.

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Most notably, Simione found that in several of the records, the unique skill and contribution of occupational therapy (“OT”) was not recognized. Medicare guidance acknowledges that OT and physical therapy (“PT”) are distinct disciplines that address different needs. *See, e.g.*, 42 C.F.R. 484.4; Medicare Benefit Policy Manual, Chp. 15, Sec. 230. Indeed, the Medicare Benefit Policy Manual explicitly states that both OTs and PTs “may be treating the patient for the same condition at different times in the same day for goals consistent with their own scope of practice.” Medicare Benefit Policy Manual, Chp. 15, Sec. 220.1.2.

The OIG reviewer appears to have disregarded this guidance, consistently deciding that OT was “duplicative” or not necessary because PT services were also provided. In each case reviewed by Simione, however, the OT services were unique and focused on functional activities of daily living such as bathing, dressing, toileting, or meal preparation, which were not addressed by the physical therapist and which were necessary components of the care plans for the patients. Again, an example is instructive.

Beneficiary #63: This was the second episode of care for a 56-year-old woman who was admitted to home health following a stay in an inpatient rehabilitation facility following a cerebrovascular accident (“CVA”)—commonly known as a stroke—that left her with residual weakness on her left side. The beneficiary has a history of CVAs and multiple falls. She also had labile blood sugars while in rehab with insulin dosage decreased due to hypoglycemia. Other diagnoses include vascular dementia, peripheral neuropathy, and obesity. She lives alone in a mobile home with intermittent assistance from a companion.

The OIG reviewer found that the OT visits were not medically necessary because they were duplicative of PT services. The OT goals, however, related to upper extremity strength and function, shower transfers, and the ability to don and doff clothing, including TED hose (designed to prevent the formation of deep vein thrombosis and pulmonary embolisms). In addition to developing an exercise program focused on shoulder strength and standing balance related to ADL performance, the OT also trained the patient in use of adaptive dressing devices and instructed her on shower and toilet transfers. These areas of self-care deficits resulting from the recent CVA were not addressed by, nor duplicative of, PT and were consistent with covered OT services as described in the Medicare Benefit Policy Manual.

In several instances the OIG reviewer also disregarded guidance related to the medical necessity of home health skilled nursing. For example, skilled nursing may be necessary for observation and assessment of a patient’s condition where there is a reasonable potential for a change that could result in modification of treatment or initiation of additional medical procedures. *See* Medicare Benefit Policy Manual, Chp. 7, Sec. 40.1.1. In addition, “[s]killed nursing visits for teaching and training activities are reasonable and necessary where the teaching or training is

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appropriate to the patient's functional loss, illness, or injury." *Id.* Sec. 40.1.2.3. While this pattern can be observed in the detailed reports provided by Simione, an example is found below.

Beneficiary 22: The beneficiary was recertified with a primary diagnosis of type II diabetes and secondary diagnoses of depression, anxiety, chronic myeloid leukemia, opioid dependence, and chronic pain. Skilled nursing notes on the recertification comprehensive assessment indicated that the reason for continuing skilled services was due to recent changes in insulin dosage and need for skilled assessment, observation, training, and teaching related to type II diabetes, medication changes, and compliance with medication administration.

The OIG reviewer determined that skilled services were not required because the beneficiary had no significant history of cognitive impairment that would impede his processing of prior educational material related to his medical condition and because he was noted to be compliant with monitoring of his diabetic status and medications. This finding is refuted by significant evidence of the need for skilled care in the medical record, however.

In addition to the recent changes in Insulin dosage, the beneficiary had two new medications: Glevec and Spironolactone, which required education and monitoring. On 2/3/15 the physician also ordered lab work to monitor the beneficiary's response to treatment and chronic conditions. Monthly lab draws were added to the plan of care, and on 3/19/15 the nurse documented obtaining a blood specimen for the lab tests. On 3/23/15 based on the skilled nurse assessment of respiratory symptoms, the physician was contacted, and an order was obtained for Levaquin. On 3/30/15 the beneficiary was assessed by the skilled nurse and found to have calf pain. The nurse contacted the physician who was concerned about the possibility of thrombophlebitis and ordered a Doppler test and to have the TENS unit the beneficiary was using checked for safety. Based on the need to alter the plan of care throughout this episode due to the beneficiary's significant diagnoses and comorbidities, the episode meets Medicare coverage criteria for skilled observation and assessment as well as teaching and training.

Once again, these examples and the others discussed in the enclosed Simione reports suggest that the OIG reviewer ignored relevant guidance, undercutting the reviewer's findings related to alleged lack of medical necessity.

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C. Billing Codes

The Draft Report also notes that for six (6) claims the medical reviewer determined that Angels Care billed Medicare with incorrectly coded claims that resulted in higher payments to the agency. Simione's findings refute this conclusion as well.

The Draft Report provides no detail to support the allegation that claims were incorrectly coded, simply stating: "certain HIPPS codes were not supported in the medical records." Draft Report at 6. Nor was any patient example provided. In each claim noted as involving incorrect billing in Appendix E, Simione calculated the HIPPS payments based on the OASIS data elements and found each claim correct as billed and paid. An example appears below.

Beneficiary #51: In the claim-specific findings provided by the OIG for this beneficiary, the OIG reviewer noted that the HIPPS code 2BGL2 was incorrectly indicated on the claim form. Simione determined that this claim was correct based on a M2200 value of 17 (16 PT and 1 OT evaluation) likely having been submitted, resulting in a billed HIPPS code of 2BGLT cross walked to 2BGL2. Because the Common Working File ("CWF") automatically adjusts claims up or down to correct for therapy need based on actual visits performed, when the adjustment to 3 therapy visits is made, the final HIPPS code is also adjusted to 1BHK2 with a payment of \$2,103.12, which is the amount that was paid.

Although it is unclear from the Draft Report why the OIG reviewer believed the codes used were incorrect, it is possible that the issues identified were related to the anticipated therapy service need, which is an estimate provided at the start of care that is automatically adjusted by the Common Working File to reflect actual therapy visits performed when the claim is paid. As shown in the example above and others found in Simione's reports, the amounts paid on each claim reflected the number of therapy visits actually performed and thus did not result in an overpayment.

D. Documentation Issues

Finally, the Draft Report states that "[f]or two of the sampled claims, the Agency incorrectly billed Medicare for home health episodes that did not meet Medicare documentation requirements." Draft Report at 7. No explanation or patient examples are provided. Based on a review of Appendix E, it appears the Draft Report is referring to claims for Beneficiaries #35 and 51. While Angels Care agrees that the claim for Beneficiary #35 was not sufficiently documented, it disagrees with respect to Beneficiary #51.

In the claim-specific findings provided by the OIG for Beneficiary #51, the OIG reviewer noted that the claim form showed skilled nursing visits billed for 1/27/15 and 1/29/15 and physical therapy services for 1/29/15 but that the record did not show that the patient was seen on those

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dates. To the contrary, documentation is present in the record for all three visits. On 1/27/15, the skilled nurse performed a physical assessment and teaching on fall prevention and safety, and on 1/29 the nurse performed a physical assessment focused on the respiratory system and teaching breathing exercises. Also on 1/29 there was a visit by the PT. Strengthening exercises were performed in sitting and standing with close assessment of vital signs to monitor tolerance to activity. Ambulation and multiple transfers were also conducted. Based on these records, it is unclear why the OIG reviewer found no record that visits had been conducted on those dates.

2. **The Statistical Sampling Methodology Used by the OIG is Unreliable and Inherently Flawed.**

The statistical sampling methodology used by the OIG is unreliable and inherently flawed, thereby calling into question the statistical validity of the extrapolated overpayment calculated by the OIG. Set forth below are examples of the various flaws in the OIG's calculations.

- The OIG reviewed only 100 claims as part of its audit. According to the Draft Report, the universe of claims during the three-year period of time under review (*i.e.*, CYs 2013, 2014 and 2015) totaled 8,914 claims. *See* Draft Report at 3-4; Appendices A and C. Thus, the number of claims in the OIG's sample comprised a mere 1.12% of the universe of claims. Because of this small sample size, the OIG's extrapolation does not have the statistical integrity required by the Medicare manuals and/or statistical industry standards, especially in light of the extrapolated overpayment amount in excess of \$5.9 million. In fact, Section 3.10.4.3 of the Medicare Program Integrity Manual specifically states that the "size of the sample (*i.e.*, the number of sampling units) will have a direct bearing on the precision of the estimated overpayment." Such a small sample does not embody the statistical validity required under the regulations, Medicare manuals, and/or statistical industry standards. Any recoupment of reimbursement should not be based on such a tenuous statistical sampling methodology.
- The universe suffers from an inherent bias due to the questionable statistical methodology used by the OIG. Specifically, the OIG acknowledged that its sampling frame (*i.e.*, universe) does not include lower paid claims of \$1,000 or less, and yet the OIG provided no explanation justifying the removal of lower paid claims from its review. *See* Appendix C to the Draft Report at 15 n.15. By intentionally removing lower paid claims from the universe, the OIG has inflated arbitrarily the dollar amounts at issue in the universe, and in so doing, the universe is inherently flawed and biased. Such bias runs afoul of the basic tenets of statistical calculations.

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- Also problematic is the OIG's improper inclusion of CY 2013 claims in its sample frame (i.e., universe), from which a stratified sample was taken, even though the OIG admitted that a portion of the CY 2013 claims were "potentially *outside* the 4-year claim-reopening period." Draft Report at 3-4 (emphasis added). Appendix C to the Draft Report makes clear that the frame included "claims for selected home health services that it provided to Medicare beneficiaries during CY's 2013, 2014, and 2015." Appendix C to the Draft Report at 15. The Appendix discusses three types of claims that *were* excluded from the frame but makes no mention of excluding CY 2013 claims. *See id.* at 15 n.15. The Draft Report elsewhere states that, nevertheless, due to the 4-year reopening time bar, overpayments associated with CY 2013 claims were addressed separately and did not factor into its calculations giving rise to the \$5.9 million extrapolated overpayment. *See* Draft Report at 3-4. As an initial matter, the OIG provided conflicting information about the number of CY 2013 claims that were reviewed but allegedly did not factor into the extrapolated overpayment. The Draft Report states that the OIG "made the Agency aware that it did not comply with Medicare billing requirements for 18 home health claims for services in CY 2013," Draft Report at 3-4 (emphasis added), but the email received from the OIG on January 19, 2018 identified 19 claims from CY 2013, *see* Exhibit B.⁸ It is also unclear from the Draft Report whether the CY 2013 claims that were excluded were for services that were *provided* in CY 2013 or claims *paid* in CY 2013. Indeed, some claims for patients with dates of service in CY 2013 *were* included in the actual overpayment calculation of \$87,631.⁹ Either way, however, neither the sample nor the frame should have included claims from CY 2013, which the OIG acknowledged it had no authority to reopen, and any extrapolated overpayment based on this flawed frame is invalid.¹⁰

⁸ The January 19, 2018 email sent by Scott Englund also states that there were two claims that were included in the 100 sampled claims but were not sent for medical review. *See* Exhibit B. It is unclear why these claims were not reviewed by the OIG reviewer, and this lack of transparency also calls into question the validity of the OIG's sample and extrapolation.

⁹ For example, Beneficiary #1 (M.L.) received home health services from 9/29/13 - 11/27/13. The OIG reviewer determined that these services did not meet Medicare coverage criteria and calculated an alleged overpayment of \$1,231.56. This overpayment associated with Beneficiary #1 appears on the first line of Appendix E to the Draft Report and is included in the actual overpayment of \$87,631 for services that the OIG claimed occurred in CY 2014 and 2015 only. *See* Draft Report at 4, 7; Appendix E. The actual overpayment of \$87,631, in turn, was then used by the OIG to calculate an extrapolated overpayment.

¹⁰ In its Draft Report, the OIG states that "[a]s of the publication of this report, this amount [\$5,917,961] may include claims outside of the 4-year claim-reopening period." *Id.* at 4-5. Once again, if the OIG included claims in its review and calculations that are outside the timeframe of its authority to reopen, any resulting overpayment, especially an extrapolated overpayment in excess of \$5.9 million is inaccurate and not supportable.

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- The OIG acknowledged that AdvanceMed conducted a non-statistical review of Angels Care that allegedly resulted in “\$63,156 in unallowable payments during the time period that is within the Medicare reopening and recovery period that *overlapped with our [OIG’s] sample frame.*” Appendix D to the Draft Report at 17 n.17 (emphasis added). The OIG explained that it accounted for this overlap by merely subtracting \$63,156 from its estimated extrapolated overpayment. *Id.* At no time did the OIG remove the claims separately reviewed by AdvanceMed from the universe of claims reviewed by the OIG, which would have been the proper approach. Simply subtracting AdvanceMed’s overpayment calculation from the OIG’s calculation does not address the inherent flaw caused by including overlapping claims in the universe. The OIG’s approach constitutes double counting and is not supportable.

Due to the reasons set forth above, as well as the overall unreliability of the sampling methodology, Angels Care objects to the extrapolated overpayment and any recoupment of its reimbursement based on such a tenuous statistical sampling methodology.

II. RESPONSE TO THE DRAFT REPORT’S SPECIFIC RECOMMENDATIONS

Your letter asks that Angels Care directly respond to each of the three specific recommendations made in the Draft Report. *See* Draft Report at 7. Angels Care responds to those recommendations as follows:

Recommendation 1: We recommend that the Agency refund to the Medicare program the \$5,917,961 in estimated overpayments received during CYs 2014 and 2015 for claims incorrectly billed that were within the 4-year claim-reopening period.

For all of the reasons articulated above, Angels Care does not concur with this recommendation. The in-depth review conducted by Simone evidences a significantly lower error rate than that calculated by the OIG reviewer, and the statistical sampling methodology used by the OIG is unreliable and inherently flawed. Angels Care agrees to refund amounts consistent with those sixteen claims for which the documentation was insufficient to support the claim as paid.

Recommendation 2: We recommend that the Agency 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.

Angels Care takes seriously its compliance with the 60-day rule but does not concur that its obligations under that rule are triggered by the Draft Report. As discussed in Section I above,

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Simone's independent review uncovered problems with only sixteen of the claims reviewed by the OIG. Specifically, Simone found insufficient documentation to support medical necessity for nine (9) claims and similarly agreed that the documentation did not support the beneficiary's homebound status in nine (9) instances. Determinations of medical necessity and homebound status are necessarily subjective, and identifying issues with only nine claims in each of these categories is not indicative of a widespread pattern or practice of improper claims submission.

Furthermore, and as the Draft Report acknowledges, the OIG's audit recommendations do not represent final determinations. The Centers for Medicare and Medicaid Services ("CMS") will subsequently determine, through a Medicare contractor, whether a potential overpayment exists, and if such an overpayment is found, Angels Care will have the right to appeal that determination. Notably, more than 60% of claims are overturned in favor of providers when heard by an administrative law judge as part of the third level of appeal. *See* Opening Statement of the Honorable Orrin Hatch, April 28, 2015 Hearing before the Finance Committee of the United States Senate, *Creating a More Efficient and Level Playing Field: Audit and Appeal Issues in Medicare*, available at <https://www.finance.senate.gov/imo/media/doc/20035.pdf>. That statistic does not include reversals that occur before or after the matter reaches an ALJ hearing. Therefore, until the appeal process is complete, it would be premature to determine whether there is a problem at Angels Care necessitating a sweeping search for additional similar overpayments. *See also* 81 F.R. 7654, 7667 (Feb. 12, 2016) ("If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.").

Recommendation 3: We recommend that the Agency strengthen its controls to ensure full compliance with Medicare requirements for billing home health services.

Angels Care always seeks to achieve full compliance with Medicare requirements for each and every home health claim it submits, and the Agency is continuously working to improve its processes. For example, AngMar Medical Holdings, the management company for Angels Care, has recently hired a clinical compliance officer with twenty-six (26) years of experience in home health as an RN, field nurse, director, administrator, and compliance officer. In addition, as referenced above, Angels Care does not concur with, and the Draft Report does not provide support for, a finding that the Agency lacks adequate controls. That finding is refuted by the independent review conducted by Simone, and Angels Care is confident that the effectiveness of its internal controls will be borne out by any future administrative appeal related to the OIG's review.

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It is for the reasons set forth above that Angels Care disagrees with the findings, recommendations, and alleged extrapolated overpayment set forth in the Draft Report. We appreciate the opportunity to provide feedback and welcome additional dialogue about the Draft Report's findings and recommendations. Should you have any questions or need additional information, please do not hesitate to contact me.

Best regards,

/Rebekah N. Plowman/

Rebekah N. Plowman, Esq.

Enc. Ex. A – Representation Authorization
Ex. B – January 19, 2018 Email from Scott Englund
Ex. C – Simione Findings