

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**EXCELLA HOMECARE BILLED  
FOR HOME HEALTH SERVICES  
THAT DID NOT COMPLY WITH  
MEDICARE COVERAGE  
AND PAYMENT REQUIREMENTS**

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**May 2019  
A-01-16-00500**

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## Report in Brief

Date: May 2019

Report No. A-01-16-00500

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



### Why OIG Did This Review

Under the 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.

Our objective was to determine whether Excella HomeCare (Excella) complied with Medicare requirements for billing home health services on selected types of claims.

### How OIG Did This Review

We selected a stratified random sample of 100 home health claims and submitted these claims to medical review.

## Excella HomeCare Billed for Home Health Services That Did Not Comply With Medicare Coverage and Payment Requirements

### What OIG Found

Excella did not comply with Medicare billing requirements for 41 of the 100 home health claims that we reviewed. For these claims, Excella received overpayments of \$129,520 for services provided in calendar years (CYs) 2013 and 2014. Specifically, Excella incorrectly billed Medicare because beneficiaries (1) were not homebound or (2) did not require skilled services. On the basis of our sample results, we estimated that Excella received overpayments of at least \$6.6 million for the CY 2013 and CY 2014 period. All of the incorrectly billed claims are now outside of the Medicare reopening period; therefore, we are not recommending recovery of the overpayments.

### What OIG Recommends and Excella Comments

We recommend that Excella 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 our recommendations. We also recommend that Excella strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services.

In written comments on our draft report, Excella disagreed with our findings and recommendations and stated that it intends to contest our findings through the appeals process. To address Excella's concerns for all claims we originally found in error, we requested our medical reviewer to again review all 70 of the claims originally found in error. Based on these reviews, our medical reviewer overturned, in part or full, 35 claims that it initially found in error. With these actions taken, we maintain that our findings and recommendations are valid.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

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

### OBJECTIVE

Our objective was to determine whether Excella complied with Medicare requirements for billing home health services on selected types of claims.

### BACKGROUND

#### **The Medicare Program and Payments for Home Health Services**

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

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

payment codes<sup>1</sup> and represent specific sets of patient characteristics.<sup>2</sup> CMS requires HHAs to submit OASIS data as a condition of payment.<sup>3</sup>

CMS administers the Medicare program and contracts with four of its Medicare administrative 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,
- HHAs did not always submit the OASIS in a timely fashion, and
- 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 section 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);

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<sup>1</sup> 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 home health agencies.

<sup>2</sup> 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.

<sup>3</sup> 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 *Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1.



- 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
- 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).<sup>4</sup>

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

### **Excella HomeCare**

Excella is a proprietary for-profit home health care provider with headquarters in Texas and a local provider office in Amesbury, Massachusetts. National Government Services, its Medicare contractor, paid this specific Excella provider approximately \$32 million for 8,800 claims for services provided in CYs 2013 and 2014 (audit period) on the basis of CMS’s National Claims

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<sup>4</sup> 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).

History (NCH) data. During the audit period, this Excella provider placed in the top 1 percent of home health providers in Medicare payments received.

## **HOW WE CONDUCTED THIS REVIEW**

Our audit covered \$30,860,249 in Medicare payments to Excella for 7,630 claims.<sup>5</sup> These claims were for home health services provided in CYs 2013 and 2014.<sup>6</sup> We selected a stratified random sample of 100 claims with payments totaling \$431,751 for review. We evaluated compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met medical necessity and coding requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). 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.<sup>7</sup>

## **FINDINGS**

Excella did not comply with Medicare billing requirements for 41 of the 100 home health claims that we reviewed. For these claims, Excella received overpayments of \$129,520 for services provided in CYs 2013 and 2014. Specifically, Excella incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound and
- services provided to beneficiaries who did not require skilled services.

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<sup>5</sup> In developing this sampling frame, we excluded from our review home health claim payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments.

<sup>6</sup> CYs were determined by the HHA claim “through” date of service. The through date is the last day on the billing statement covering services provided to the beneficiary.

<sup>7</sup> Sample items may have more than one type of error.

These errors occurred primarily because Excella did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas. On the basis of our sample results, we estimated that Excella received overpayments of at least \$6,636,091 for the audit period.<sup>8</sup>

## **EXCELLA BILLING ERRORS**

Excella incorrectly billed Medicare for 41 of the 100 sampled claims, which resulted in overpayments of \$129,520.

### **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) and Revision 172 of section 30.1.1 (effective November 19, 2013) covered different parts of our audit period.

Revision 1 states that for a patient to be eligible to receive covered home health services under both 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

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<sup>8</sup> We report overpayments at the lower limit.

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.

Revision 172 states that for a patient to be eligible to receive covered home health services under both 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.

#### *Excella Did Not Always Meet Federal Requirements for Home Health Services*

For 28 of the sampled claims, Excella incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirements<sup>9</sup> for being homebound for the full episode (20 claims) or for a portion thereof (8 claims).<sup>10</sup>

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<sup>9</sup> All 28 claims had dates of service during the period covered by Revision 172 of section 30.1.1.

<sup>10</sup> Of these 28 claims with homebound errors, 10 claims were also billed with skilled services that were not medically necessary. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

### **Example 1: Beneficiary Not Homebound – Entire Episode**

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The physical therapy evaluation documentation for one beneficiary showed that, from the start of the episode, the patient was ambulating several hundred feet without an assistive device, was independent with transfers, and had good overall strength in her lower extremities. For the entire episode, leaving the home did not require a considerable or taxing effort.

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### **Example 2: Beneficiary Not Homebound – Partial Episode**

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For another beneficiary, records showed that the patient was initially homebound, as she was thought to require care in the home setting due to needing a cane and the assistance of another person to ambulate, having significant weakness and being at an increased risk for falls due to polypharmacy, disease process, and numerous comorbidities. By a later date in the episode, she was able to transfer and ambulate 200 feet with a rolling walker without hands-on assistance. She was residing in an accessible assisted living facility without mobility barriers. Leaving the home would no longer require a considerable or taxing effort.

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These errors occurred because Excella did not have adequate oversight procedures to ensure that it verified and continually monitored the homebound status of Medicare beneficiaries under its care and properly documented the specific factors that qualified the beneficiaries as homebound.

### **Beneficiaries Did Not Require Skilled Services**

#### *Federal Requirements for 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 1835(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).<sup>11</sup> Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or

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<sup>11</sup> 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

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).

### *Excella Did Not Always Meet Federal Requirements for Skilled Services*

For 23 of the sampled claims, Excella incorrectly billed Medicare for an entire home health episode (2 claims) or a portion of an episode (21 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.<sup>12</sup>

#### **Example 3: Beneficiary Did Not Require Skilled Services**

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A beneficiary with chronic obstructive pulmonary disease and a history of a fractured clavicle was homebound. The beneficiary developed a pressure sore, and skilled nursing services were ordered to provide wound care. Excella provided skilled nursing care to the homebound beneficiary. However, the beneficiary's wound healed part way through the episode, and the beneficiary could have been discharged at that time with no need for the subsequent skilled nursing services.

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These errors occurred because Excella did not always provide sufficient clinical review to verify that beneficiaries initially required skilled services or continued to require skilled services.

#### **OVERALL ESTIMATE OF OVERPAYMENTS**

On the basis of our sample results, we estimated that Excella received overpayments totaling at least \$6,636,091 for the audit period.

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other things (the Manual, chapter 7, § 40.1.2).

<sup>12</sup> Of these 23 claims with skilled need services that were not medically necessary, 10 claims were also billed for beneficiaries with homebound errors. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

## RECOMMENDATIONS

We recommend that Excella:

- for the estimated \$6,636,091 overpayment for all claims outside of the Medicare 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;
- 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 procedures to ensure that:
  - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and
  - beneficiaries are receiving only reasonable and necessary skilled services.

### EXCELLA HOMECARE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

#### EXCELLA HOMECARE COMMENTS

In written comments on our draft report, Excella disagreed with all four of our original recommendations. (The draft report had four recommendations, which we have revised to three.) For the first recommendation, to refund overpayments for incorrectly billed claims,<sup>13</sup> Excella disagreed with our medical review decisions and maintained that all of the sample claims were billed correctly. Excella stated that medical reviewers (1) impermissibly used ambulation distances as a “rule of thumb” in determining beneficiary homebound status, (2) applied the wrong homebound coverage criteria for claims with dates of service prior to November 2013, (3) failed to account for corrections to OASIS coding made prior to submission of the claims, and (4) “effectively determined” that assisted living facility (ALF) residents can almost never qualify for skilled occupational therapy services. In addition, Excella stated that our medical reviewer was predisposed to finding a high error rate. Further, Excella stated that

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<sup>13</sup> The first recommendation in the draft report was to refund to the Medicare program the portion of the estimated overpayment for claims incorrectly billed that are within the reopening period. We have since removed this recommendation because all of the incorrectly billed claims are now outside of the reopening period.

the sampling methodology used to project our overpayment was fundamentally unreliable because we did not specify in advance the criteria used for the extrapolation and did not produce sufficient information for Excella to conduct a complete review of the methodology. Excella stated that it intends to contest the adverse claim determinations and our statistical sampling methodology in the Medicare administrative appeals process.

Regarding our second and third recommendations, to exercise reasonable diligence to identify and return overpayments in accordance with the 60-day rule,<sup>14</sup> Excella did not concur, as it plans to appeal our overpayment assessment through the Medicare appeals process for reasons described above. For our fourth recommendation, to strengthen its procedures to ensure that (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and (2) beneficiaries are receiving only reasonable and necessary skilled services, Excella did not concur, as it maintains that it is committed to strict adherence with all applicable Medicare coverage, documentation, coding and billing requirements. Excella stated that it has policies and procedures in place, including a quality assurance program, to ensure that the homebound status of its patients is monitored and that patients only receive skilled treatment that is medically necessary and commensurate to their unique needs.

We have included Excella's comments in their entirety as Appendix F.<sup>15</sup>

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

We agree with Excella that our medical reviewer applied the wrong homebound coverage criteria for claims with dates of service prior to CMS's November 2013 criteria clarification. To address this issue and Excella's other concerns about the claims we originally found in error, we requested our medical reviewer to again review all 70 claims originally found in error. This additional review considered the original records provided by Excella and supplemental information Excella provided with its comments to our draft report. Based on these reviews, our medical reviewer overturned, in part or in full, 35 claims that it initially found in error. With these actions taken, we maintain that our findings and recommendations, as revised, are valid. We acknowledge Excella's right to appeal our findings.

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<sup>14</sup> The second and third recommendations in the draft report were as follows: (1) for the remaining portion of the estimated overpayments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return any overpayments in accordance with the 60-day rule and (2) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule.

<sup>15</sup> Excella also included a comprehensive appendix to its comments. This document includes a claim-by-claim rebuttal to the claim findings in our draft report. However, this document contains personally identifiable information, so we excluded it from this report.



Below is a summary of the reasons Excella did not agree with our findings and recommendations and our responses.

## **BENEFICIARY HOMEBOUND STATUS**

### **Excella Comments**

Excella stated that medical review determinations pertaining to noncompliance with homebound requirements were flawed because medical reviewers did not correctly apply Medicare coverage criteria, impermissibly used ambulation distance as a “rule of thumb” to establish homebound status, improperly predicated coverage on the accessibility features of the ALFs, and improperly applied other Medicare homebound criteria in several unique cases.

### **Office of Inspector General Response**

We agree with Excella that our medical reviewer incorrectly applied Medicare coverage criteria in evaluating the homebound status of beneficiaries for the 29 claims with dates of service prior to November 19, 2013. We acknowledge that CMS changed the definition of “confined to the home” found in chapter 7, section 30.1.1 of the Manual via Change Request 8444/Transmittal 172, effective November 19, 2013. We requested that our medical reviewer review those affected error claims again. All 29 error claims were overturned, and we adjusted our findings accordingly.

Ambulation distance is one factor among others that our medical reviewer considered in making homebound determinations. Our medical reviewer prepared detailed medical review determination reports documenting relevant facts and their analysis. These were provided to Excella prior to issuing our draft report. 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 record. Our medical reviewer carefully considered 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 the reviewer considered in making the homebound determination. This is evident from the relevant facts and discussion included in the individual decisions.

Excella acknowledged to us that it serves a large population of ALF residents. According to Excella, “there is no support in the law for the notion that architectural features of a beneficiary’s residence are dispositive as to homebound status.” However, Excella does not cite to any law, regulation, or CMS guidance directing that the physical characteristics of a

patient's home may not be considered in making a determination of homebound status. Moreover, our medical reviewer did not consider beneficiaries' residences to be a dispositive factor, but one of many it deliberated upon when analyzing the unique circumstances of each beneficiary.

As set forth in the Manual, chapter 7, section 30.1.1,<sup>16</sup> the second requirement for being homebound is that there must exist a normal inability to leave home and that leaving the home must require a considerable and taxing effort. CMS guidance provides the following example of a homebound patient, which references the physical characteristics of the living environment:

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists would be . . . . A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence (the Manual, chapter 7, § 30.1.1).

Physical barriers in the home environment are relevant to the homebound assessment under the "normal inability" and "considerable and taxing effort" requirement (Criterion Two). Although the patient is the focus of the homebound requirement, the lack of physical access barriers in an ALF, as in a private residence, is a factor in determining whether a beneficiary is homebound under Criterion Two. For example, a patient residing in a walk-up but who no longer can negotiate steps or stairs has a "normal inability" to leave home, and leaving a home with that physical characteristic would require a "considerable and taxing effort." This may not be the case for the same patient in a residence without steps or stairs. The physical characteristics of the home environment, however, are always considered along with the patient's condition.<sup>17</sup>

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

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

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

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

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

In further comments on our draft report, Excella challenged the medical review determinations of several "unique cases" for improper application of Medicare homebound guidelines. Excella contends that in several such cases, our medical reviewer concluded that patients were not homebound because they had not experienced a new or impairing injury during the episode of care. However, our medical reviewer considered the patients' entire clinical course. Contrary to Excella's statement, a "new injury or impairing condition" would be part of the overall assessment in meeting Criterion Two of the homebound determination because a patient's clinical course must be taken into consideration. For instance, a postoperative patient would be expected to improve over time, so the duration of the illness and whether the patient had received inpatient rehabilitation may be factors in meeting the criteria. Nevertheless, a "new or impairing condition" is not a sole factor in making a homebound determination, and our medical reviewer properly considered it as simply one factor in making its homebound determinations.

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

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 medical reviewer followed in its reviews.

Excella also asserted that the medical reviewers failed to adequately consider many beneficiaries' cognitive limitations when making homebound determinations. We agree that cognitive impairment must be considered in making a homebound determination. Our medical reviewer 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 reviewer considered in making homebound determinations.

As part of our additional review request, our medical reviewer reviewed the original records submitted by Excella and the supporting rationales provided in Excella's comments on our draft report for all homebound errors originally cited in our draft report. We reversed 29 claims that we had identified as errors in our draft report and adjusted our findings accordingly.<sup>18</sup>

## **MEDICAL NECESSITY**

### **Excella Comments**

Excella disputed all medical review determinations related to claims with services found to be not medically necessary. Excella stated that the medical reviewers' decisions often failed to

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<sup>18</sup> While we reversed the homebound errors in these 29 claims, many of these error claims also had medical necessity issues that remained as findings.

account for the beneficiaries' unique conditions and specialized clinical needs. In addition, Excella asserted that medical reviewers appeared to believe that ALF residents rarely qualify for occupational therapy services because custodial care is available from facility staff. Excella stated that custodial care provided by ALF staff cannot serve as a substitute for skilled therapy services. In each of the relevant cases, Excella said its licensed occupational therapists evaluated the beneficiaries and identified clear deficits warranting skilled intervention. Excella said the fact that an ALF staff member may have been available to help a beneficiary take a shower or get dressed, for example, does not mean that the beneficiary did not deserve a chance to improve his or her ability to safely and independently perform those same tasks. In other cases, Excella stated that medical reviewers appeared to have misapplied or been unfamiliar with Medicare coverage guidelines for certain skilled services.

### **Office of Inspector General Response**

Our medical reviewer did not categorically deny ALF residents skilled occupational therapy services based on the availability of custodial caregivers in an ALF. Their determinations were made in accordance with the Manual, chapter 7, section 40.2. Per 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:

While a patient's particular medical condition is a valid factor in deciding if 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.

The patient remains the focus of the determination, and skilled occupational therapy services may be needed to educate caregivers and establish a home exercise plan, assess the environment for adaptive equipment needs, provide education in the use of adaptive equipment, etc. We acknowledge that these tasks require skilled services and cannot simply be handled by caregivers.

As stated earlier, we submitted each claim that we identified as an error in our draft report to additional review by our medical reviewer, who considered the originally submitted records as well as the supporting rationale provided by Excella in its comments on our draft report. All claims found to be in error associated with the above-mentioned ALF issues were submitted to this additional review. Our medical reviewer also reviewed those error claims with unique conditions and specialized clinical needs and those claims where Excella believed that our

medical reviewers had misapplied or been unfamiliar with Medicare coverage guidelines for certain skilled services. Upon additional review, our medical reviewer overturned 5 of the 35 original medical necessity error determinations, and we adjusted our findings accordingly.

## **HEALTH INSURANCE PROSPECTIVE PAYMENT SYSTEM CODING**

### **Excella Comments**

Excella stated that the five claims<sup>19</sup> with HIPPS coding discrepancies identified by the medical reviewers did not constitute clerical errors on Excella's part but rather oversights by the medical reviewers. Excella stated that these claims were submitted to quality assurance reviews. These reviews resulted in amendments to the OASIS assessment data. According to Excella, the OASIS correction documentation was present in the charts, but the medical reviewers failed to account for this information.

### **Office of Inspector General Response**

We requested that our medical reviewer additionally review its determinations for claims identified in our draft report with HIPPS coding errors. Our medical reviewer stated that there was an error in the home health grouper program used in its reviews. Accordingly, all HIPPS coding errors originally identified in our draft report were reversed, and we adjusted our findings accordingly.

## **OIG'S MEDICAL REVIEW CONTRACTOR WAS PREDISPOSED TO FINDING A HIGH ERROR RATE**

### **Excella Comments**

Excella commented that OIG's contracted medical reviewer is a longstanding CMS Qualified Independent Contractor (QIC) involved in the Medicare Part A appeals process. Excella stated that this QIC has a high unfavorable decision rate in its appeals reviews. Excella contended that the medical review contractor "rubber stamps" claim denials by Medicare administrative contractors (MACs), decisions which were, to a large degree, later reversed by other adjudicators in the appeals process. Excella cited online CMS data showing the overturn rates by our medical reviewer in its Part A QIC work for the years 2010 through 2015. This data reflects that the QIC generally issued unfavorable decisions over 80 percent of the time. Excella also cites to Administrative Law Judge (ALJ) decision data in its premise that "large numbers" of

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<sup>19</sup> Our draft report identified three claims under the "Incorrectly Billed Health Insurance Prospective Payment System Code" caption. These three claims contained services that were appropriate but were incorrectly coded. An additional two sample claims with HIPPS coding errors were also identified with medical necessity issues. In replicating the claims, we grouped the dollar errors identified under the "Beneficiaries Did Not Require Skilled Services" caption.

the unfavorable QIC decisions were reversed at the ALJ level. In addition, Excella made note of our refusal to provide curricula vitae of OIG's contracted medical reviewers. Excella stated that our refusal to provide any background information or details related to the qualifications of the reviewers represents a lack of transparency and calls into question whether GAGAS requiring sufficient competence, expertise, and technical knowledge on the part of auditors and specialists were met.

### **Office of Inspector General Response**

We disagree that our medical review contractor was predisposed to finding a high error rate. The QIC data referenced by Excella is based on appeals filed by providers who (typically) have experienced a denial pursuant to a MAC review. The CMS QIC contract is entirely separate from the OIG medical review contract. Each of these contracts makes use of a separate team of contractor employees who are responsible for meeting the requirements of separate and distinct statements of work. OIG does not oversee the CMS QIC contract and cannot opine on the favorable or unfavorable decision rate under that contract. Further, given the differences in the two statements of work, OIG cannot draw any conclusion based on an attempted comparison of the favorable and unfavorable rates between the two contracts. The claims the QIC reviewed were originally denied by a MAC as having indications of noncompliance with Medicare regulations. Conversely, our home health sample cases in this audit passed MAC coverage edits and were paid. Our sample was a randomly drawn stratified sample drawn from a population of these paid claims. Thus, there would be no common rate of denial between the two samples, and any comparison of rates from the two groups is meaningless. Accordingly, Excella's contention that our medical reviewer was predisposed to issue unfavorable decisions in review of this sample of home health cases is unfounded and is not substantiated by any data.

We do not agree with Excella's contention that we are not in compliance with GAGAS because we did not provide specific information about individual medical reviewers. OIG conducted a full and open competition when it signed the contract under which these reviews are conducted. As part of that competition, OIG evaluated the offerors' understanding of the project and its technical approach, the qualifications of its personnel and its ability to assemble an appropriately skilled team, and the quality assurance and project management plans it submitted. OIG determined that the awardee was a responsive and responsible bidder and represented the best value to the Government. The Request for Proposal also included a description of the review process and the oversight provided by the contractor's medical director or physician, OIG contracting officer representative, and other OIG representatives. For example, the contract required that all claims with a medical necessity determination be reviewed by two clinicians before being provided to OIG. The second-level reviews were to be conducted by the medical director or a physician with the same

qualifications with experience in the appropriate specialty under review. All reviewers were also required to be free of any conflict of interest.

## **OIG'S OVERPAYMENT PROJECTION IS UNRELIABLE AND FLAWED**

### **Excella Comments**

Excella broadly asserted that OIG has not identified or followed any set guidelines for its sampling and extrapolation procedures. Specifically, Excella stated that OIG did not set forth sampling and extrapolation criteria, in contravention of GAGAS. Excella also stated, in commenting upon correspondence from OIG that stated that 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[,]” that there is no general “legal standard” for the use of extrapolation in audits such as this one. Moreover, Excella contended that the legal cases OIG cited in that same correspondence do not stand for the proposition that extrapolation is always statistically valid just by defining the sampling frame and sampling unit, randomly selecting the sample, applying relevant criteria in evaluating the sample, and using statistical sampling software to apply the correct formulas for the extrapolation. Excella further asserted that OIG has refused to furnish Excella with complete information related to its sampling methodology. Specifically, Excella contended that it is missing the universe of claims necessary to validate the sampling frame. Excella stated that its statistician may not be able to perform a complete analysis of the sampling methodology without the file from which the sampling frame was constructed. Excella conceded that OIG provided sampling materials that included, but were not limited to, a copy of the sampling plan, a list of random numbers used to select the sample, and RATS-STATS output from the extrapolation process.

### **Office of Inspector General Response**

We disagree that our sampling methodology and overpayment projection is unreliable and flawed. We conducted and reported our audit in accordance with GAGAS. Section 7.13 of GAGAS (2011 Revision) states that when sampling significantly supports the auditor’s findings, conclusions, or recommendations, the report should describe the sample design and state why the design was chosen, including whether the results can be projected to the intended population. We thoroughly describe our sampling and estimation methodology in Appendix C of our report.

Excella’s statement that there is no “legal standard” for sampling and extrapolation in OIG audits is correct in the sense that there is no one standard methodology written into law. However, our statement that 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, is correct. Federal courts and the Medicare Appeals Council have stated that there is no formally



recognized generally accepted statistical principles and procedures. We performed our statistical sampling in a valid scientific manner based on considerable institutional knowledge and experience that can be replicated by any professional statistician. Moreover, our methods are consistent with those that have been repeatedly upheld in prior Federal court and Medicare Appeals Council decisions.<sup>20</sup> To account for our sampling methodology in a manner that is generally favorable to the provider, we report estimated overpayments at the conservative 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 total in the sampling frame 95 percent of the time.

We provided Excella with all the information necessary to replicate the sample from the sampling frame and recalculate the overpayment estimate amount included in the report. In addition, Excella has direct access to the claim information necessary to validate the sampling frame and we subsequently provided Excella with a listing of the claims in the sampling frame, which matched our population. With knowledge of our methodology and the actual data used to perform our sampling and extrapolation, Excella offered no specific objections to our stated methodology.

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<sup>20</sup> 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); *Ratanasen v. California Dept. Of Health Serv.* 11 F.3d 1467 (9th Cir. 1993).

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$30,860,249 in Medicare payments to Excella for 7,630 home health claims with episode-of-care through dates in CYs 2013 and 2014. From this sampling frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$431,751.

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

We limited our review of Excella'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 fieldwork at Excella from January 2016 through February 2017.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted Excella's paid claim data from CMS's NCH file for the audit period;
- removed payments for low utilization payment adjustments, partial episode payments, and requests for anticipated payments from the population to develop our sampling frame;
- selected a stratified random sample of 100 home health claims totaling \$431,751 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 Excella to support the claims sampled;

- reviewed sampled claims for compliance with known risk areas;
- 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;
- reviewed Excella’s procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the patients in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample to estimate the total Medicare overpayments to Excella for our audit period (Appendix D);
- discussed the results of our review with Excella officials; and
- requested our medical reviewer review the additional documentation provided by Excella in its comments on our draft report.

We conducted this performance audit in accordance with GAGAS. 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 § 484.210(e); 74 Federal Register 58078, 58110 (Nov. 10, 2009); and *CMS’s Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1).

### **COVERAGE AND PAYMENT REQUIREMENTS**

To qualify for home health services, Medicare beneficiaries must (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy, speech-language pathology, or occupational therapy;<sup>21</sup> (3) be under the care of a physician; and (4) be under a plan of care that has been

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<sup>21</sup> 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, a physical therapy service, or a 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)).

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).

Per 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 Act<sup>22</sup> 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.<sup>23</sup>

### **Confined to the Home**

For 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.

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<sup>22</sup> 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.

<sup>23</sup> See 42 CFR § 424.22(a)(1)(v) 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.

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) and Revision 172 of section 30.1.1 (effective November 19, 2013) covered different parts of our audit period.

Revision 1 states that for a patient to be eligible to receive covered home health services under both 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, a patient 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.

Revision 172 states that for a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is confined to his or her home. For purposes of the statute, an individual shall 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.

## **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).

### *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)(1)(v)) 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.



In addition, the Manual (chapter 7, § 30.5.1) states that the certifying physician must document the encounter either on the certification, which the physician signs and dates, or a signed addendum to the certification.

### *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 consisted of Excella's claims for select home health services<sup>24</sup> that it provided to Medicare beneficiaries with episodes of care that ended in CYs 2013 and 2014.

### SAMPLING FRAME

The sampling frame, which matched our population, consisted of a database of 7,630 home health claims, valued at \$30,860,249, from CMS's NCH file.

### SAMPLE UNIT

The sample unit was a home health claim.

### SAMPLE DESIGN

We used a stratified random sample.

Stratum	Amount Range of Claims Paid	Number of Claims	Total Dollar Value of Claims
1	\$1,476.89 to \$4,496.87	4,895	\$15,063,197.67
2	\$4,500.50 to \$15,425.26	2,735	15,797,052.02
<b>Total</b>		<b>7,630</b>	<b>\$30,860,248.69</b>

### SAMPLE SIZE

We randomly selected 50 claims from stratum 1 and 50 claims from stratum 2. Our total sample size was 100 claims.

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<sup>24</sup> We excluded home health payments for low utilization adjustments, partial episode payments, and requests for anticipated payments.

## **SOURCE OF RANDOM NUMBERS**

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

## **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in each stratum, and after generating the random numbers, we selected the corresponding frame items for review.

## **ESTIMATION METHODOLOGY**

We used the OAS statistical software to estimate the total amount of overpayments paid to Excella during the audit period. 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 are designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

<b>Stratum</b>	<b>Frame Size</b>	<b>Total Value of Frame</b>	<b>Sample Size</b>	<b>Total Value of Sample</b>	<b>Incorrectly Billed Sample Items</b>	<b>Value of Overpayments In Sample</b>
1	4,895	\$15,063,197	50	\$155,665	13	\$36,074
2	2,735	15,797,052	50	276,086	28	93,446
<b>Total</b>	<b>7,630</b>	<b>\$30,860,249</b>	<b>100</b>	<b>\$431,751</b>	<b>41</b>	<b>\$129,520</b>

**ESTIMATES**

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

Point estimate	\$8,643,134
Lower limit	6,636,091
Upper limit	10,650,177

**APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM**

**STRATUM 1 (Samples 1–25)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Overpayment</b>
1	-	-	-
2	-	-	-
3	-	-	-
4	X	-	\$2,982
5	-	-	-
6	-	-	-
7	X	-	2,398
8	-	-	-
9	-	-	-
10	-	-	-
11	-	-	-
12	X	-	2,543
13	-	X	2,629
14	-	-	-
15	-	-	-
16	X	-	4,234
17	-	X	2,110
18	-	-	-
19	-	-	-
20	-	-	-
21	-	-	-
22	-	-	-
23	X	X	2,849
24	X	-	2,127
25	-	-	-

**STRATUM 1 (Samples 26–50)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Overpayment</b>
26	-	-	-
27	-	-	-
28	-	-	-
29	X	-	\$2,617
30	-	-	-
31	-	-	-
32	-	-	-
33	-	-	-
34	-	-	-
35	-	-	-
36	X	-	3,612
37	X	-	2,427
38	-	-	-
39	-	-	-
40	-	-	-
41	-	-	-
42	X	-	3,262
43	-	-	-
44	X	-	2,284
45	-	-	-
46	-	-	-
47	-	-	-
48	-	-	-
49	-	-	-
50	-	-	-

**STRATUM 2 (Samples 51–75)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Overpayment</b>
51	X	-	\$5,202
52	X	-	3,674
53	-	-	-
54	-	-	-
55	-	-	-
56	-	-	-
57	-	-	-
58	-	X	1,187
59	-	-	-
60	-	X	2,499
61	X	-	5,264
62	X	X	6,105
63	-	-	-
64	-	-	-
65	X	X	2,390
66	-	X	1,946
67	X	X	4,921
68	X	X	2,522
69	X	-	5,800
70	-	X	489
71	-	X	2,524
72	-	-	-
73	-	-	-
74	-	X	1,986
75	-	-	-

**STRATUM 2 (Samples 76–100)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Overpayment</b>
76	X	-	\$3,663
77	-	-	-
78	-	-	-
79	-	-	-
80	-	-	-
81	-	-	-
82	X	X	4,624
83	X	-	643
84	X	X	5,446
85	-	-	-
86	-	-	-
87	-	-	-
88	-	X	1,681
89	-	-	-
90	X	X	2,095
91	X	-	7,099
92	-	-	-
93	X	X	5,615
94	X	-	5,750
95	-	X	1,900
96	X	X	1,665
97	-	X	4,741
98	-	X	1,986
99	-	X	29
100	-	-	-
<b>Total</b>	<b>28</b>	<b>23</b>	<b>\$129,520</b>



**Excella HomeCare, Inc.**

**Response to Draft OIG Report No. A-01-16-00500**

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## I. INTRODUCTION

Excella HomeCare, Inc. (“Excella” or “Agency”) hereby submits this response to the draft report (“Report”) issued by the Office of Inspector General (OIG) as to report number A-01-16-00500. For the reasons discussed below, Excella disputes the findings set forth in the Report and does not concur with any of the OIG’s related recommendations.

## II. BACKGROUND

Excella has provided high quality home health services to the elderly and medically fragile residents of Massachusetts for more than a decade. Excella specializes in providing in-home skilled nursing and therapy services to residents of Assisted Living Facilities (ALFs), many of whom are Medicare beneficiaries.<sup>1</sup> A commonly-held but false assumption is that ALF residents receive more care than their community-dwelling peers. Such an assumption is inaccurate insofar as ALF residents tend to be frailer, suffer more chronic conditions, and ultimately require more frequent care than individuals who reside independently in the community. Facility staff, moreover, often require more training as to resident care because they are responsible for a significantly larger number of patients than their private duty counterparts.<sup>2</sup>

Excella’s patients are, on average, 86 years old.<sup>3</sup> The most common diagnoses for an Excella patient fall into the following three categories: mental health conditions (62%), neurological disorders (43%), and injuries (e.g., fractures) (19%).<sup>4</sup> As shown by its census demographics, Excella’s patients are also more clinically complex than the average patient receiving home health services. A significantly larger percentage are, for example, incontinent of urine, at risk for pressure ulcer development, at risk for falls, and exhibit memory impairment relative to the national averages.<sup>5</sup>

Condition	Excella / 2013-2014	National Average	Excella / 2016-2017	National Average
Bladder Incontinence	74%	55%	77%	58%
Pressure Ulcer Risk	64%	48%	64%	48%
Fall Risk	97%	90%	99%	94%
Memory Deficit	55%	17%	60%	17%

<sup>1</sup> Under Massachusetts state law, ALF staff are prohibited from furnishing skilled care to residents. 651 Mass. Code Regs. § 12.04(3). Skilled care includes, but is not limited to, administration of injectable medications, wound care, observation and evaluation of an unstable patient’s medical condition, insertion and irrigation of catheters, and physical / occupational / speech therapy. 130 Mass. Code Regs. § 456.409(A).

<sup>2</sup> During OIG’s audit period from 2013 to 2014, for example, Excella staff assessed 55% of caregivers (virtually all of whom were ALF staff) as requiring training to properly assist patients with performance of their activities of daily living (ADLs) relative to only 22% of caregivers around the country who required similar instruction. The Agency’s clinical staff also determined during the same time period that 35% of facility caregivers required education as to medication administration (compared with a national average of 20%) and 71% required training on proper methods for supervising patient safety (compared with 12% nationally).

<sup>3</sup> The average home care patient in the country, by contrast, is 75 years old.

<sup>4</sup> This data is current as of 2016 and 2017. By way of comparison, 26% of home care patients in the country have been diagnosed with mental illnesses, 28% have been diagnosed with neurological conditions, and 12% have injury-related diagnoses.

<sup>5</sup> This data has been gleaned from the Agency’s CASPER reports from July 2013 to July 2017.

The clinically complex nature of Excella’s patient population, in turn, means that the Agency’s patients present with a higher risk for hospitalization than the average home care patient. Hospitalization risk is assessed according to metrics such as a recent decline in mentation, a history of falls, and polypharmacy (i.e., taking five or more medications), among others.<sup>6</sup>

Metric	Excella / 2013-2014	National Average	Excella / 2016-2017	National Average
Decline in Mentation	32%	14%	51%	17%
History of Falls	48%	32%	49%	32%
Polypharmacy	90%	87%	94%	91%

Along with the CMS-mandated Outcome and Assessment Information Set (OASIS), Excella routinely performs a host of individually-tailored assessments to better address the unique clinical needs and functional deficits of its patients.<sup>7</sup> These assessments include but are not limited to the Allen Cognitive Levels Scale, the Berg Balance Test, the Tinetti Assessment, the Missouri Alliance for Home Care (MAHC-10) Fall Risk Assessment, the Timed Up and Go (TUG) test, and the Cornell Depression Scale. The Agency also administers specialized testing as to sensory function, swallowing capabilities, and visual acuity where indicated. Due to its large number of patients with cognitive impairments, Excella also maintains a nationally-recognized memory care program overseen by trained occupational therapists and speech-language pathologists.

Despite the clinically challenging nature of its patient census, Excella is able to furnish higher quality home health services and achieve better outcomes relative to its peers around the country. Excella’s clinical staff presently includes clinicians who hold certifications in the following areas: lymphedema treatment; infusion therapy; wound, ostomy, and continence care; dementia care; and LSVT® BIG therapy. From 2013 to 2014, only 9% of the Agency’s patients were hospitalized within 30 days of admission to home health services compared with 12% nationally. This metric underscores the high quality of services furnished by Excella, and this achievement is in spite of the fact that the Agency’s average length of stay is lower than the national average.<sup>8</sup> In this way and through the provision of high quality home health services generally, Excella reduces the need for additional, more costly healthcare services – such as hospital admissions.

In addition to clinical excellence, Excella is committed to maintaining robust compliance with applicable federal and state laws.<sup>9</sup> For example, the Agency engages consultants to perform reviews of 10% of the records for its active patient census on a quarterly basis using a comprehensive, 39-point audit tool that incorporates Medicare regulations, manual provisions, local coverage determination (LCD) criteria, and other coverage guidelines.<sup>10</sup> At the conclusion of these audits, the consultants present a report summarizing their findings to Agency leadership.

<sup>6</sup> See Centers for Medicare and Medicaid Services (CMS), *OASIS-C2 Guidance Manual*, Ch. 3 at C-17 (Jan. 1, 2017).

<sup>7</sup> Every OASIS assessment is reviewed by a clinician who holds a Clinical OASIS Specialist (COS-C) certification prior to submission to the state repository.

<sup>8</sup> During the audit period, the average length of stay for an Excella patient was 50 days compared with the national average of 59 days. Similarly, the Agency’s average length of stay of 56 days in 2016 and 2017 remained lower than the national average of 58 days.

<sup>9</sup> Excella staff provided the OIG with a summary of its internal compliance procedures, along with copies of the pertinent policies and procedures, during the entrance conference.

<sup>10</sup> Excella staff are required to participate in annual compliance training.

Excella creates an action plan within 72 hours of receipt of the consultants' report to address any noted deficiencies. Each subsequent quarterly audit then evaluates how well the Agency remedied any deficiencies noted in prior reviews.<sup>11</sup> Excella's quarterly record review processes, in addition to the countless other policies and procedures in place to ensure adherence to applicable laws and regulations, is a prime example of the Agency's culture of compliance.

### III. STATEMENT OF NONCONCURRENCE

For the reasons given below and as discussed herein, Excella does not concur with the recommendations set forth in OIG's Report.

**OIG Recommendation #1:** We recommend that Excella refund to the Medicare program the portion of the estimated \$13,024,364 overpayment for claims incorrectly billed that are within the reopening period.

**Excella Response:** Excella does not concur with this recommendation because none of the sample claims was billed incorrectly. As explained in greater detail below, the OIG's medical review decisions are flawed for a host of reasons. For example, the decisions impermissibly used ambulation distance as a "rule of thumb" for determining beneficiary homebound status, applied the wrong coverage criteria to claims with dates of service prior to November 2013, improperly failed to account for corrections to OASIS coding made prior to submission of the claims, and effectively determined that ALF residents can almost never qualify for skilled occupational therapy services, among other errors.<sup>12</sup> The sampling methodology used to project the alleged overpayment, furthermore, is fundamentally unreliable because OIG did not specify in advance the criteria used for the extrapolation and has refused to produce sufficient information for Excella to conduct a complete review of the methodology. For these reasons, Excella intends to vigorously contest the adverse claim determinations and the validity of the OIG's statistical sampling methodology in the Medicare administrative appeals process. Excella anticipates that the alleged overpayment will be eliminated entirely, or at least reduced considerably, during the course of its appeal. Any refund to the Medicare program at this juncture would thus be premature.

**OIG Recommendation #2:** We recommend that Excella, for the remaining portion of the estimated \$13,024,364 overpayment for claims that are outside of the Medicare 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.

**Excella Response:** Excella acknowledges its legal obligation to, upon receipt of credible information that an overpayment may exist, exercise reasonable diligence to identify such potential overpayment(s) within the preceding 6 years.<sup>13</sup> The Report states that OIG believes its findings

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<sup>11</sup> The results of the quarterly chart audits are a mandatory agenda item for Excella's Quality Assurance and Performance Improvement (QAPI) Committee, which carefully reviews all action plans created by Agency leadership for completeness and efficiency. The QAPI Committee may also revise and update any action plans, as appropriate.

<sup>12</sup> Excella's bases for disagreeing with the OIG's claim determinations are set forth more fully in the succeeding sections of this response as well as **Appendix A**.

<sup>13</sup> 42 C.F.R. § 401.305.

constitute credible information so as to trigger the exercise of reasonable diligence by Excella. While the Agency appreciates the OIG's recommendation and is fully committed to refunding any legitimate overpayments (if it identifies any), Excella does not concur because it intends to challenge the OIG's overpayment assessment through the Medicare appeals process. As CMS has noted, a provider may, following receipt of an audit-related overpayment notice, reasonably determine that it is premature to conduct an additional investigation as to the existence of additional potential overpayment while it appeals the audit findings:

[W]e recognize that in certain cases, the conduct that serves as the basis for [a] contractor identified overpayment may be nearly identical to conduct in some additional time period not covered by the contractor audit. 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.<sup>14</sup>

In this case, Excella reasonably believes that an investigation to identify other potential overpayments is not warranted at this time since the OIG's medical review decisions are incorrect and will be quickly reversed on appeal.

**OIG Recommendation #3:** We recommend that Excella 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.

**Excella Response:** Excella disagrees with this recommendation for the same reason it does not concur with the OIG's second recommendation.

**OIG Recommendation #4:** We recommend that Excella strengthen its procedures to ensure that the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented and beneficiaries are receiving only reasonable and necessary skilled services.

**Excella Response:** As discussed at length in the preceding section, Excella is committed to strict adherence with all applicable Medicare coverage, documentation, coding, and billing requirements. The OIG has not identified any specific flaws in Excella's QAPI process or its compliance program. Excella has policies and procedures in place to ensure that the homebound statuses of its patients are monitored and that patients only receive skilled treatment that is medically necessary and commensurate with their unique needs. Accordingly, the Agency does not concur with the OIG's recommendation that Excella implement further policies and procedures as described in the Report since they would be redundant.

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<sup>14</sup> Medicare Program; Reporting and Returning Overpayments, 81 Fed. Reg. 7,654, 7,667 (Feb. 12, 2016).

#### IV. THE OIG'S MEDICAL REVIEW AND CODING DETERMINATIONS ARE CONTRARY TO LAW AND INCONSISTENT WITH THE BENEFICIARIES' UNIQUE MEDICAL NEEDS AS WELL AS THE CONTENTS OF THE MEDICAL RECORDS

Excella's general responses to the OIG's medical review and coding decisions are set forth below. The Agency has also composed claim-specific summaries for each of the denied or repriced claims explaining why the applicable coverage and coding criteria have been met. Those summaries are attached hereto as **Appendix A**.

##### A. Beneficiary Homebound Status

The most prevalent "error" identified among the sample claims relates to beneficiary homebound status. Of the 70 claims that were denied or repriced, the reviewers concluded that beneficiaries were not homebound for all or part of the episodes in 57 cases. All such determinations are flawed, however, because they did not correctly apply Medicare coverage criteria, impermissibly used ambulation distance as a "rule of thumb" to establish homebound status, and were improperly predicated on the accessibility features of the ALFs.

##### 1. The medical reviewers failed to consider that CMS substantively revised Medicare homebound guidelines effective November 2013.

The Medicare statute states the following with respect to beneficiary homebound status:

[A]n individual *shall* be considered '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.<sup>15</sup>

CMS has promulgated its interpretation of this statute in the Medicare Benefit Policy Manual (MBPM).<sup>16</sup> From the time at which the MBPM was adopted until November 2013, the homebound guidelines set forth in the manual stated in pertinent part:

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, a patient *will be* considered to be homebound if they have a condition

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<sup>15</sup> 42 U.S.C. § 1395f(a)(8) (emphasis added).

<sup>16</sup> See, e.g., *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 101 (1995) (describing a Medicare manual as a set of "interpretative rules...that advise providers how [CMS] will apply the Medicare statute and regulations...").



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.<sup>17</sup>

Effective November 19, 2013, CMS revised its interpretation of the homebound statute as embodied in the MBPM.<sup>18</sup> This new manual interpretation stated in relevant part:

For purposes of the statute, an individual shall be considered ‘confined to the home’ (homebound) *if the following two criteria are met:*

1. 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.

2. Criterion Two

- There must exist a normal inability to leave home;

**AND**

- Leaving home must require a considerable and taxing effort.<sup>19</sup>

The OIG’s decisions as to claims with dates of service prior to November 19, 2013 do not account for this change in Medicare policy. Although the Report states that “the requirements were the same”<sup>20</sup> in both versions of the manual, such a reading of the rules is, as one federal appeals court recently observed, “far from obvious or obviously correct.”<sup>21</sup>

The MBPM provision in effect prior to November 2013 clearly stated that a beneficiary “will be” considered homebound if he or she cannot leave home except with the aid of a supportive device, the use of special transportation, the assistance of another person, or if leaving home is medically contraindicated. This stood in stark contrast to another paragraph in the same manual

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<sup>17</sup> MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 1) (2003) (emphasis added).

<sup>18</sup> CMS, *Home Health – Clarification to Benefit Policy Manual Language on Confined to the Home Definition*, Transmittal 172 / Change Request 8444 (Oct. 18, 2013), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R172BP.pdf> (last accessed October 3, 2017).

<sup>19</sup> MBPM Ch. 7 § 30.1.1 (Pub. 100-02, Rev. 172) (2013) (emphasis added).

<sup>20</sup> Report at 5, n.8.

<sup>21</sup> *Caring Hearts Pers. Home Servs. v. Burwell*, 824 F.3d 968, 972 (10<sup>th</sup> Cir. 2016).

provision which, as noted above, stated that a beneficiary's condition "should be" such that there exists a normal inability to leave home and that leaving would require a considerable and taxing effort.<sup>22</sup> CMS' previous use of the hortatory language "should be" suggests that provision contained a useful but not necessarily dispositive test for beneficiary homebound status.<sup>23</sup> The fact that a beneficiary was unable to leave home except with a supportive device or the assistance of another person, on the other hand, would have been sufficient to render him or her confined to the home.

Other facets of the structure and content of the previous version of the MBPM lend support to Excella's position. For example, the manual stated that a beneficiary "will be" considered homebound where it was medically contraindicated for he or she to leave home. The MBPM thus appeared to contemplate that some beneficiaries would be homebound even if they could have left home without a considerable and taxing effort.<sup>24</sup> Similarly, the manual sets forth several examples of beneficiaries whom CMS would consider to be homebound. These examples included the following:

- A patient who is blind or senile and requires the assistance of another person in leaving his or her place of residence.
- A patient with arteriosclerotic heart disease of such severity that he or she must avoid all stress and physical activity.
- A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe for the patient to leave home unattended, even if he or she has no physical limitations.<sup>25</sup>

All of these patients would presumably be able to leave home without a considerable or taxing effort. Blindness or a psychiatric disorder do not, in and of themselves, imply any physical limitations that would cause the beneficiary to expend significant effort when leaving home. In fact, the third example explicitly states that CMS would consider the beneficiary homebound even in the absence of a considerable and taxing effort to leave home.

The distinction between the two versions of the homebound guidelines is important because, among the 57 claims where the reviewers raised homebound issues, 27 of them (or approximately 47%) had dates of service prior to November 19, 2013. Yet the matrix used by the medical review contractor to audit the claims completely failed to recognize this distinction, as illustrated by the excerpt reproduced below:

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<sup>22</sup> *Cf. id.* at 972-73.

<sup>23</sup> *Id.* at 972.; *see also Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 661-62 (2007) (the word "shall" generally conveys mandatory intent).

<sup>24</sup> *See Caring Hearts*, 824 F.3d at 973.

<sup>25</sup> MBPM Ch. 7 § 30.1.1.

Factors for Determination	Medicare Authority
Patient is homebound	42 CFR §§409.42 and 409.47; CMS Publication 100-02 (Benefit Policy Manual), Chapter 7, §30.1 – 30.1.2
<ul style="list-style-type: none"> <li>• To leave home needs supportive device, special transport, or assist from another person due to illness/injury; OR has a condition that makes leaving the home contraindicated</li> </ul> <p>If YES, then:</p> <ul style="list-style-type: none"> <li>• The patient normally is unable to leave the home, except on an intermittent basis AND leaving the home requires considerable and taxing effort</li> </ul> <p>If YES, then:</p> <ul style="list-style-type: none"> <li>• The patient is not residing at a facility providing inpatient care</li> </ul>	

Consequently, claims comprising 47% of those denied or repriced due to alleged “errors” related to homebound status were simply assessed using the incorrect coverage criteria. The OIG should accordingly resubmit the affected claims to its medical review contractor for new determinations based on the proper coverage guidelines.

**2. The medical reviewers impermissibly used ambulation distance as a “rule of thumb” to determine homebound status.**

One of the most consistent facts asserted (uniformly void of context) in the adverse homebound determinations is patient ambulation distance. In virtually every case where a claim was denied in whole or in part because the beneficiary was allegedly not homebound, the reviewers made mention of the fact that the patient was able to ambulate a certain distance at the start of care or as of the date of disallowance. In many cases, ambulation distance was the *only* basis given in support of the unfavorable decisions. For example, the reviewer determined that beneficiary S1-25 was not homebound for the following reason:

The patient was homebound at the start of care due to dementia and emotional lability and was weakened with pneumonia and influenza. However, by [approximately one month into the episode] he was able to ambulate 200 feet, which is more than household distances, and to transfer without hands-on assistance.<sup>26</sup>

In the case of beneficiary S2-41, the reviewer similarly concluded:

<sup>26</sup> The medical reviewers frequently observed that a beneficiary’s ability to ambulate anywhere from 100 to 200 feet was “greater than household distances.” While this may be accurate where a beneficiary lives in a private residence, almost all of the patients here resided in ALFs. The facilities were, for home health coverage purposes, the beneficiaries’ residences. See MBPM Ch. 7 § 30.1.2. A distance of 200 feet, for example, in the context of a large, sprawling facility should thus not qualify as a “household distance.”

The patient was not homebound for the entire length of this episode. At the start of care the patient was able to ambulate 100 feet with a rolling walker. This is greater than household distances. He was residing in an accessible assisted living facility. At the second physical therapy visit he was ambulating 200 feet. He was not homebound during the episode of care; leaving the home would not require a considerable or taxing effort.

As these examples, which are by no means exhaustive, readily illustrate, the medical reviewers have treated ambulation distance as dispositive to beneficiary homebound status. This is both clinically inappropriate and contrary to Medicare coverage guidelines.

The Report correctly states that a home health coverage determination must be predicated on objective, clinical evidence regarding the beneficiary's individual need for care.<sup>27</sup> For this reason, the MBPM explicitly disallows the use of "rules of thumb" when rendering coverage decisions:

Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, or specific treatment norms is not appropriate.<sup>28</sup>

Any presumption or general precondition that fails to account for a beneficiary's individual care needs, therefore, constitutes an improper "rule of thumb."<sup>29</sup> A decision that a beneficiary is not homebound because he or she can ambulate for a certain distance would indisputably qualify as a "rule of thumb" because it constitute a presumption unrelated to the beneficiary's unique clinical condition as a whole and effectively creates a new coverage requirement for home health eligibility.<sup>30</sup>

Assuming for the sake of argument that the medical reviewers have not utilized such a "rule of thumb," the reviewers' decisions as based on ambulation distance would nevertheless remain clinically flawed because they are not predicated on objective, clinical evidence and fail to account for the beneficiaries' individual care needs.<sup>31</sup> The fact that a beneficiary may be able to ambulate for 100 or 200 feet during a physical therapy session inside of an ALF, on even surfaces, using an assistive device, and under close supervision (or, in many cases, with hands-on assistance) from a licensed therapist does not demonstrate that the patient would possess sufficient functional mobility so as to be able to leave the facility safely and independently. The same would hold true for other types of functional movements, such as transfers. The Medicare Appeals Council, the adjudicative body responsible for issuing final administrative decisions as to Medicare claim appeals on behalf of the Secretary of Health and Human Services, has previously considered and rejected a similar approach to assessing beneficiary homebound status:

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<sup>27</sup> Report at 3; *see also* 42 C.F.R. § 409.44(a).

<sup>28</sup> MBPM Ch. 7 § 20.3.

<sup>29</sup> *See, e.g., Jimmo v. Sebelius*, 2011 WL 5104355, at \*4-6 (D. Vt. 2011) (discussing the Plaintiffs' allegation that the "Improvement Standard" was an impermissible rule of thumb on which Medicare coverage of therapy services was conditioned).

<sup>30</sup> *Cf. id.*

<sup>31</sup> *Cf.* 42 C.F.R. § 409.44(a); MBPM Ch. 7 § 20.3.

Turning to the factors which the [Administrative Law Judge] did discuss in determining that beneficiaries were not homebound, we find that, in many cases, the ALJ appears to have given decisive weight to aspects of the beneficiaries' condition that do not necessarily evidence that they were able to leave home safely at all or without considerable and taxing effort. For example, the ALJ relied on findings in OASIS reports that a beneficiary was independent with some or all basic activities of daily living (ADLs), without acknowledging that an ability to eat, dress, toilet, or bathe oneself is not equivalent to the ability to leave the house safely and without considerable effort. Nor does the ability to independently transfer from bed to chair or on to and off of a toilet imply sufficient independent mobility outside the home.<sup>32</sup>

The Council's point here is that any analysis of a beneficiary's homebound status must consider the safety with which the beneficiary would be able to *leave* home and / or the degree of effort that would be required for the beneficiary leave his or her residence. The OIG's adverse homebound determinations in this case fail that test. The singular focus on patient mobility *inside* of the home thus cannot and should not serve as a basis to conclude that the patient is not homebound.

In almost all cases, the reviewers' myopic focus on ambulation distance was also unreasonable because the resulting decisions did not account for a host of other clinically relevant facts, such as the patients' shortness of breath on exertion, balance impairments, poor safety awareness, and cognitive limitations. For example, the medical reviewer concluded that beneficiary S1-8 was not homebound because:

The patient was not homebound at the start of care. She had been treated for bronchitis and there was no new impairing condition. She had previously been independent with a rollator walker and had received inpatient rehabilitation after the acute hospitalization. She had done very well in rehabilitation and had increased her functional independence. She was able to ambulate and perform mobility related activities of daily living without hands-on assistance and lived in an accessible ALF. Leaving the home would not require a considerable or taxing effort.

As with the examples provided in the preceding paragraph, the reviewer focused almost exclusively on the degree to which S1-8 could perform functional mobility tasks and ambulate inside of the ALF but utterly failed to consider her otherwise extensive limitations.

Beneficiary S1-8 was an elderly female who had one lung and suffered from chronic obstructive pulmonary disease (COPD).<sup>33</sup> She became noticeably short of breath when performing activities such as dressing, using the restroom, and walking distances less than 20 feet. She also exhibited poor endurance and depended on a walker for safe ambulation. Upon her admission to home health services, a physical therapist evaluated S1-8 with gait deviations in the form of a

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<sup>32</sup> *In the case of Quality Home Health Services, Inc.*, 2009 WL 10487060, at \*6 (H.H.S. 2009). Excella recognizes that Council decisions are not binding on the OIG. But such decisions are relevant insofar as they represent the Secretary's interpretation of Medicare coverage guidelines as applied to the specific facts of a particular case.

<sup>33</sup> The beneficiary's other comorbidities included gait abnormality, dementia, anemia, rheumatic heart disease, thrombocytopenia, hyperthyroidism, and myeloproliferative disorder.

narrow base of support, short step length, and poor foot clearance. S1-8's balance was impaired and she was at high risk for falls, as evidenced by her Tinetti Assessment score of 15/28. The patient took 29 seconds to complete the TUG test, which demonstrated her functional mobility was compromised. Throughout the physical therapy evaluation, S1-8 exhibited shortness of breath and reported to the therapist that, "My breathing is my biggest problem."

Throughout the episode under review, the clinicians regularly assessed S1-8 with dyspnea on exertion such that her endurance and functional mobility were limited. For example, during one therapy session the patient became increasingly short of breath when performing balance exercises and ADL activities and her respiration rate increased to 28 breaths per minute with activity. Similarly, while participating in gait training during a subsequent session, S1-8 was able to ambulate for an overall distance of 200 feet but required multiple rest breaks due to fatigue and shortness of breath. These facts support that S1-8 was, contrary to the medical reviewer's flawed decision, confined to her home secondary to shortness of breath with exertion, impaired balance, and low endurance.

The case of S1-8 illustrates that many of the adverse homebound determinations are not only misguided from a clinical perspective but also incomplete bordering on purposefully misleading. The rationale offered by the reviewer fails to even mention this patient's shortness of breath or other functional limitations. The fact that S1-8's respiration rate increased with activity and that she required standing rest breaks during gait training secondary to shortness of breath, for example, are far more relevant to the patient's homebound status than whether she required hands-on assistance to perform her ADLs or whether she was able to walk for 200 feet inside, on a level surface, and with the assistance of a physical therapist.

### **3. The reviewers incorrectly determined that many beneficiaries were not homebound because they resided in "accessible assisted living facilities."**

In the majority of cases, the reviewers concluded that beneficiaries were not homebound at least in part because they resided in "accessible" ALFs.<sup>34</sup> Neither the Report nor the individual claim determinations define the term "accessible assisted living facility," and it does not appear in any Medicare rules or regulations. Nevertheless, it is apparent that the reviewers considered the structural features of the patients' ALFs when rendering the individual claim decisions. There is no support in the law for the notion that the architectural features of a beneficiary's residence are dispositive as to homebound status. These considerations are hardly relevant to beneficiary homebound status, and the resulting adverse decisions are thus contrary to law.

The homebound guidelines set forth in the Medicare statute and CMS coverage criteria require an analysis of the beneficiary's ability to leave his or her residence safely and independently. And the ease with which a patient can enter or exit an ALF, however, would only be marginally relevant to that analysis. The case of beneficiary S1-12 is instructive. This was an elderly female whose medical history was significant for epilepsy, hypertension, osteoarthritis, angina, hyperlipidemia, and arthritis. She was hard of hearing, had poor endurance, and depended

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<sup>34</sup> The reviewers mentioned this fact in the following cases: S1-4, S1-5, S1-8, S1-10, S1-12, S1-16, S1-19, S1-23, S1-24, S1-42, S1-45, S2-5, S2-7, S2-10, S2-11, S2-14, S2-18, S2-19, S2-21, S2-25, S2-26, S2-33, S2-35, S2-40, S2-41, S2-44, S2-45, S2-45, S2-48.

on a walker to ambulate safely. S1-12 was admitted to Excella to receive intermittent skilled nursing care after undergoing a procedure to remove skin cancer from her left cheek. The medical reviewer stated the following with respect to this case:

The patient was not homebound at the start of care. She was status post treatment for squamous cell cancer of the left cheek; there was no other injury or impairing condition. She had a slow but steady gait with a walker and was residing in an accessible assisted living facility. Leaving the home would not require a considerable or taxing effort. Skilled nursing was needed for wound care and assessment for signs and symptoms of infection. However, this could have been done on an outpatient basis and did not require the home setting. Outpatient medical care would have met this patient's needs.

The thrust of this decision is that S1-12 resided in an "accessible assisted living facility" and that she would have been able to leave the facility on a regular basis to obtain healthcare treatment. Given her functional limitations and other impairments, the summary provided below constitutes a probable description of the effort required for S1-12 to leave her home for a physician appointment:

- To prepare to leave her residence, S1-12 would need to bathe, groom, and dress herself. She required supervision to groom herself and dress her upper body and hands-on assistance for lower body dressing and bathing, so her facility caregivers would assist her in safely completing these tasks. S1-12 became short of breath when performing tasks such as dressing herself or using the restroom, so she would also likely need at least one rest break during this process.
- Using her walker, she would need to ambulate from her apartment to the facility parking lot. She became short of breath when walking distances less than 20 feet, so she would presumably need to take more than one rest break to make it to the parking lot. S1-12 was also at increased risk for falls (as per her MAHC-10 score of 6) and reported dizziness secondary to a new seizure medication, so she would also likely require assistance from another person for safety while ambulating.
- S1-12, using her walker and with the assistance of another person, would need to transfer into a vehicle and tolerate a trip to the physician's office.
- Upon arrival at the physician's office, she would need to transfer out of the vehicle, use her walker to navigate uneven (and unfamiliar) terrain, and negotiate the doorway to the physician's office. She would likely need to take a rest break inside of the physician's office secondary to dyspnea and / or dizziness.
- S1-12 had a memory deficit and suffered intermittent confusion, so she may require assistance to check herself in at the physician's office and discuss her medical condition with the doctor.
- Following her appointment, the patient would exit the physician's office using her walker, negotiate unlevel surfaces, and transfer into a vehicle. She would likely be short of breath

at that time and would have required assistance from another person to ambulate and transfer in to the vehicle due to her increased fall risk and periodic dizziness.

- S1-12 would finally return to the ALF where she resided. She would need assistance to transfer out of the vehicle and obtain her walker. She would then return to her apartment, likely stopping for multiple rest breaks before reaching her destination.

As this example illustrates, the accessibility and physical structure of a residence is of limited relevance to the question of whether a beneficiary is homebound. The fact that the ALF in which S1-12 resided may have been equipped with a ramp at the facility entrance, for example, would have had minimal bearing on the patient's overall ability to leave her home safely and independently.

Most states, including Massachusetts, also strictly regulate architectural and structural features of ALFs so as to promote accessibility and minimize mobility barriers.<sup>35</sup> Accepting the medical reviewer's determinations in many cases that residing in an accessible ALF is sufficient to undermine a beneficiary's homebound status (or, at a minimum, would be a significant factor weighing against home confinement), then this rule would effectively exclude all or most ALF residents from eligibility for the Medicare home health benefit. This result would be contrary to the Medicare statute as well as CMS policy.<sup>36</sup>

#### **4. The medical reviewers have generally and improperly applied other Medicare homebound guidelines in several unique cases.**

Several other homebound decisions reflect additional errors that, while not thematic or recurring in nature, nonetheless resulted in the incorrect decisions that the beneficiaries were not confined to their homes.

##### **(a) Recent injuries or newly-impairing conditions are not required to render a beneficiary homebound.**

In several cases, the medical reviewers concluded that beneficiaries were not homebound in large part because they had not suffered any new injuries or impairing conditions.<sup>37</sup> There is no such requirement in Medicare coverage criteria for homebound status, and it is entirely possible that a beneficiary could be rendered homebound by the effects of longstanding deficits or chronic conditions. The MBPM contains several examples of beneficiaries whom CMS would consider to be homebound.<sup>38</sup> In many of those examples, the beneficiaries suffered from chronic conditions, such as hemiplegia or paralysis due to cerebrovascular disease, blindness, senility, Amyotrophic Lateral Sclerosis (ALS) or some other neurodegenerative condition, arteriosclerotic heart disease, or psychiatric illness. Despite the absence of a new injury or impairing condition, CMS would consider the beneficiaries in the MBPM examples to be homebound. This demonstrates that, in all

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<sup>35</sup> See, e.g., 651 Mass. Code Regs. § 12.04(1).

<sup>36</sup> See MBPM Ch. 7 § 30.1.2(A) (ALF can serve as a beneficiary's residence for home health purposes).

<sup>37</sup> The reviewers mentioned this fact in the following cases: S1-5, S1-8, S1-12, S1-21, S1-36, S1-44, S2-13, S2-14, S2-16, and S2-17.

<sup>38</sup> See MBPM Ch. 7 § 30.1.1.



applicable cases, the medical reviewer's unfavorable homebound determinations are inconsistent with Medicare policy.

**(b) Leaving home does not preclude a beneficiary from qualifying as homebound.**

In some cases, the medical reviewers determined that beneficiaries were not homebound at least in part because they left their ALFs during the episodes. For example, the reviewer concluded that beneficiary S2-7 was not homebound in part because, "The record shows that the member was able to leave the facility for nonmedical reasons, such as attending family functions." This observation is both misleading and does not reflect proper application of Medicare coverage guidelines.

At the time of the episode in question, S2-7 was a male beneficiary who was incontinent of bladder, hard of hearing, had poor endurance, and depended on a walker for safe ambulation. The patient also became dyspneic with moderate exertion and was at risk for falls. On *one* occasion during the episode, S2-7 left his ALF to go out to dinner with his family to celebrate his birthday. The reviewer's determination as to S2-7's claim is misleading insofar as it suggests the patient left home multiple times; the record reflects he only left once. In addition, the decision is contrary to Medicare coverage guidelines, which permit beneficiary absences from the home under certain circumstances. The MBPM explains:

[O]ccasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain healthcare provided outside rather than in the home.<sup>39</sup>

In this case, the record reflects that S2-7 left his home once in 60 days, so the absence should qualify as "infrequent." Going to a restaurant to celebrate his birthday with his family, moreover, would almost certainly constitute a "unique event" similar to a family reunion or graduation. The fact that S2-7's family took him to a restaurant to celebrate his birthday therefore should not disqualify him from the Medicare home health benefit.<sup>40</sup>

In another case, the reviewer concluded that beneficiary S1-44 was not homebound in part because, "She was able to be seen on an outpatient basis for a routine electrocardiogram." At the time of service, this beneficiary was 86 years old and had a medical history relevant for depression, generalized muscle weakness, dementia, hypertension, osteoporosis, hyperlipidemia, angina, and a myocardial infarction. She was incontinent of urine, had impaired cognition, exhibited poor endurance, required assistance to ambulate safely, and was at increased risk for falls. Her physician ordered an EKG because she was considering an adjustment to one of the beneficiary's

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<sup>39</sup> MBPM Ch. 7 § 30.1.1.

<sup>40</sup> Cf. *Dennis v. Shalala*, 1994 WL 708166, at \*4-5 (D. Vt. 1994) ("The obvious thrust is that the definition of 'confined to home' should not serve to imprison the elderly by creating a penalty of loss of Medicare benefits for heroic attempts to live a normal life.").

medications. The fact that S1-44 went to her physician's office for this test does not, according to the plain language of the pertinent coverage criteria, undermine the patient's homebound status. The MBPM could not be clearer on this issue: "Any absence of an individual from the home attributable to the need to receive health care treatment...*shall not* disqualify an individual from being considered to be confined to his [or her] home."<sup>41</sup> This example illustrates yet again that the medical reviewers have deviated from CMS coverage criteria in attempting to justify their adverse decisions.

**(c) The medical reviewers failed to adequately consider many beneficiaries' cognitive limitations.**

As discussed in section II, Excella treats a significantly higher percentage of patients with cognitive limitations, such as memory deficits or impaired decision-making capabilities, than the national average. In many cases, these types of cognitive limitations render beneficiaries homebound. This is entirely consistent with CMS policy, as the MBPM contains the following example of a homebound beneficiary: "A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is of such a nature that it would not be considered safe for the patient to leave home unattended, even if they have no physical limitations."<sup>42</sup> The facts from many denied claims are largely congruent with this example, which strongly indicates that the reviewers have failed to properly apply Medicare coverage guidelines.

The case of S1-44, discussed in the preceding section, is illustrative. Due to her dementia, this patient suffered cognitive impairments in the form of a memory deficit, confusion, disorientation, and impaired decision-making. During the initial start-of-care assessment, the registered nurse assessed her as being oriented only to person and place. She was unable to recall how many children she had, state her full name and address, or identify the neighborhood where she lived. In spite of these obvious limitations, the medical reviewer determined the patient was not homebound based on the following:

She was able to ambulate with a rolling walker and physical therapy was being requested for progression to a cane. Although she had reported cognitive impairment, she was aware of her forgetfulness; there was no new injury or impairing condition. She was able to be seen on an outpatient basis for a routine electrocardiogram. Leaving the home would not require a considerable or taxing effort.

This decision is flawed in that it fails to adequately consider the unique facts of this beneficiary's case.

The record amply supports that S1-44 was homebound secondary to cognitive impairment, memory loss, and poor safety awareness. For this reason, it would have been manifestly unsafe for this patient to leave her home unattended. For example, in the first week of the episode the patient reported she could not remember details from her husband's funeral, which had occurred approximately two weeks beforehand. Approximately two weeks later, the home health nurse arrived at the facility for a scheduled visit to find S1-44 wandering the halls and unable to locate

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<sup>41</sup> MBPM Ch. 7 § 30.1.1 (emphasis added).

<sup>42</sup> *Id.*

her apartment (she was also unable to access her apartment because she had lost her keys). Several weeks after that, the home health nurse recorded that the patient had awoken twice during the previous night and gotten dressed, but the patient was unable to recall doing so. These facts readily support that, consistent with the MBPM, S1-44's cognitive limitations rendered her homebound.

The medical reviewer brushes aside the patient's cognitive limitations by observing that S1-44 was aware of her memory loss. This is absurd. The fact that a patient who suffers from advanced Alzheimer's disease may be able to state his or her diagnosis, for example, does not mean that it would be safe for that person to leave home unassisted. The record in this case supports that S1-44 could not state her name or address or even find her own apartment within the ALF, nor could she recall events from the preceding hours (such as where she left her keys), days (such as getting dressed twice during the night), or weeks (such as her own husband's funeral). The notion that a beneficiary with such severe cognitive impairments would have been able to leave her ALF safely and unassisted is simply not credible.

In another case, the reviewer concluded that a beneficiary who suffered from cognitive deficits was homebound at the start of care but inexplicably ceased being homebound later in the episode. This beneficiary, S1-25, was an 80 year-old male who resided in the memory care unit of an ALF. His medical history was significant for Alzheimer's disease and dementia, among other comorbidities. During the initial comprehensive assessment of the patient, the clinician evaluated S1-25 with impaired decision-making, memory loss (to the extent that constant supervision was required), and the need for cueing and direction several times throughout the day. Nevertheless, the reviewer concluded that S1-25 was not homebound during part of the episode in question:

The patient was homebound at the start of care due to dementia and emotional lability and was weakened with pneumonia and influenza. However, [approximately mid-way through the episode], he was able to ambulate 200 feet, which is more than household distances, and to transfer without hands-on assistance.<sup>43</sup>

As of the date of disallowance, S1-25 still suffered from Alzheimer's disease and dementia with resulting cognitive limitations. For example, during a nursing visit two days prior to the date S1-25 allegedly ceased being homebound, the clinician documented:

[Patient] sitting in common area. Ambulated with [patient] and his [walker] back to his room. ***[Patient] needed a great deal of cueing and physical assistance to get safely to his room.*** He was frequently forgetting walker. Arrived at room, sat down, and then said he needed the bathroom. Assisted with clothing and safety. After [he] finished [he] was focused on leaving his room. (emphasis added).

This patient was barely even able to make it safely from the common area of the facility to his apartment without "a great deal of" assistance, much less leave the ALF safely and independently. The notion that S1-25 was no longer homebound as of the date of disallowance is unsupported by the record and contrary to CMS coverage criteria.

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<sup>43</sup> This rationale also illustrates the reviewers' improper, near-exclusive reliance on ambulation distance for determining beneficiary homebound status, as discussed in section IV.A.2.

## **B. Medical Necessity**

In 35 out of 70 cases, the medical reviewers determined that at least some of the skilled services provided during the episodes were allegedly not medically reasonable or necessary. The majority of these decisions involve partial denials whereby the reviewers concluded that skilled care should have ceased at an earlier date than the treating physicians and clinicians believed it would have been appropriate to do so. In addition, the reviewers routinely denied occupational therapy services simply because the patients resided in ALFs where custodial care was available. In other cases, the reviewers appear to have misapprehended or were unfamiliar with certain Medicare coverage criteria for specific skilled services. Consequently, Excella disputes all such determinations for the reasons summarized below and discussed in more detail in the attached summaries.

### **1. The reviewers' decisions often failed to account for the beneficiaries' unique conditions and specialized clinical needs.**

As discussed in section IV.A.2, Medicare regulations and CMS policy mandate that home health coverage determinations take into consideration each beneficiary's unique condition and individual care needs.<sup>44</sup> In many cases, the medical reviewers, often with little or no written justification, determined that patients did not require skilled care at all or that the skilled services should have been discontinued long before the beneficiary had met his or her treatment goals. All such decisions were rendered in error because they did not comport with Medicare coverage guidelines.

In one case, the reviewers determined that S1-49, a 79 year-old stroke patient with right-sided hemiplegia, aphasia, and contractures, did not require physical therapy for skilled maintenance services. The reviewer opined:

[T]he patient did not have skilled needs. The [cerebrovascular accident] was more than twenty years prior and she was receiving maintenance therapy treatments that could have been provided by her non-skilled caregivers. There was no new injury or impairing condition. The daily home exercise program (HEP) better met this patient's needs and did not require ongoing skilled therapy services.

This barebones conclusion does not account for the beneficiary's unique condition, which included difficulty communicating secondary to aphasia, contractures to her right lower extremity, and intermittent pain to various parts of her body.<sup>45</sup> An unskilled caregiver overseeing a rudimentary home exercise program (HEP) would not have been able to ensure that the HEP was effective at maintaining the beneficiary's level of function given her overall condition. The reviewers also ignored the fact that, on most occasions, the physical therapist adjusted the treatment to specifically address the beneficiary's condition, such as by providing manual therapy techniques or joint

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<sup>44</sup> See 42 C.F.R. §§ 409.44(a), 409.44(b)(1)(i), and 409.44(b)(3)(i)-(iii); MBPM Ch. 7 §§ 20.3, 40.1.1, and 40.2.1.

<sup>45</sup> The reviewer also implied that a "new injury or impairing condition" was required for the beneficiary to receive maintenance services. This is not required by Medicare coverage guidelines. In addition, this observation would seem to contravene the very purpose of maintenance therapy in the first instance, which is designed for patients suffering from chronic conditions. See 42 C.F.R. § 409.44(c)(2)(iii)(C).

mobilization. A caregiver who lacked the knowledge, skills, and training of a physical therapist would not have been able to effectively administer such services.

In another case, beneficiary S2-23 was admitted to the hospital for treatment of pneumonia and a urinary tract infection (UTI). After she was released from the hospital, she was admitted to Excella to receive, among other services, physical therapy. Her medical history was significant for congestive heart failure, hypertension, dementia, atrial fibrillation, and hyperlipidemia. The reviewers determined that S2-23 required physical therapy for only part of the episode under review, reasoning that:

Skilled physical therapy was needed to progress the patient's mobility and to reduce her burden of care as much as possible. Education and training in terms of a maintenance home exercise program with assistance from her caregivers was indicated. However, after [approximately two weeks of services] PT could have been discharged as the training had been completed.

This decision utterly failed to mention that S2-23 suffered several exacerbations in her condition and setbacks with treatment after the date of disallowance, which would have justified ongoing physical therapy.<sup>46</sup> For example, she began to exhibit increased confusion two weeks later and was found to have a sodium imbalance. Shortly thereafter, she was diagnosed with another UTI after suffering increased confusion. Approximately one week later, she sustained a fall from her couch and reported soreness and pain to her right shoulder. If S2-23 had not been permitted to complete her physical therapy treatments, then her onsets of confusion would have likely inhibited carryover of the instructions provided by the therapist and she would not have received any treatment for her shoulder injury.

The two examples provided in this section demonstrate that, in many cases, the medical reviewers have offered only the barest of rationales for decisions that plainly failed to take into account the beneficiaries' unique conditions and individualized needs. The OIG should therefore reconsider its decisions that some or all of the skilled services provided in 35 of the cases under review were not medically reasonable and necessary.

**2. The medical reviewers appear to believe that ALF residents rarely qualify for occupational therapy services because custodial care is available from the facility staff.**

The reviewers appear to have developed another "rule of thumb" during the course of the audit: ALF residents generally do not qualify for occupational therapy services since the facility staff would be available to assist with ADLs and self-care tasks.<sup>47</sup> These unlawful decisions constitute another theme throughout the OIG's flawed audit.

Custodial care cannot serve as a substitute for skilled therapy services. In each of the relevant cases, licensed occupational therapists evaluated the beneficiaries and identified clear

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<sup>46</sup> S2-23 had also not met all of her treatment goals as of the date of disallowance.

<sup>47</sup> The medical reviewers raised this issue in the following cases: S2-8, S2-12, S2-14, S2-16, S2-17, S2-18, S2-19, S2-32, S2-38, S2-41, S2-43, S2-45, and S2-50.

deficits warranting skilled intervention. The patients were willing to participate in therapy and the services were commensurate with their needs as identified in the initial evaluations and any subsequent reassessments. The fact that an ALF staff member may have been available to help a beneficiary take a shower or get dressed, for example, does not mean that the beneficiary did not deserve a chance to improve his or her ability to safely and independently perform those same tasks.

For instance, beneficiary S2-41, an ALF resident, suffered an ischemic stroke which left him with right-sided weakness, hemiparesis, and dysarthria. Following treatment in the hospital and a skilled nursing facility, he returned home with orders from his physician to be admitted to Excella for skilled nursing and therapy services, including occupational therapy. A licensed occupational therapist evaluated the patient with deficits related to upper extremity strength, balance, and performance of ADLs such as dressing, toileting, grooming, bathing, and tub transfers. In spite of this patient's clear need for skilled services, the medical reviewer dismissively concluded:

[T]he need for skilled OT services is not established. The member was residing in an assisted living facility with caregivers and was able to perform essential activities of daily living without hands on assistance. There was no medical necessity for occupational therapy services.<sup>48</sup>

The fact that ALF staff may have been available to assist S2-41 with his ADLs does not disqualify this patient from eligibility for skilled care. The patient was entitled by law to the opportunity to receive skilled services to enhance his ability to safely and independently care for himself and improve his quality of life. The medical reviewer's decision in this case, and all other similar cases, must therefore be reassessed and appropriately modified.

### **3. In many cases, the reviewers appear to have misapplied or been unfamiliar with Medicare coverage guidelines for certain skilled services.**

There are several cases where it would appear from the rationales for the unfavorable coverage decisions that the reviewers are unfamiliar with some aspects of home health coverage criteria. Several examples are given below. Excella respectfully requests that the OIG reconsider all such determinations based on the coverage provisions referenced herein.

In one case, a physician ordered home health services for his diabetic patient primarily for the purpose of preparing and administering the patient's daily insulin injections. This patient, S2-7, was an elderly male who also suffered from depressive disorder, hypertension, and osteoarthritis. He required skilled nursing care for insulin administration due to a significant memory deficit and impaired fine motor skills. In cases such as this, the MBPM explicitly states that preparation and administration of the patient's insulin injection constitutes a skilled nursing service:

[W]here a patient is either physically or mentally unable to self-inject insulin and there is

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<sup>48</sup> The phrase "essential activities of daily living" does not appear in Medicare coverage guidelines. The distinction between an "essential" ADL and a "non-essential" ADL is also not entirely clear.

no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service.<sup>49</sup>

The medical reviewer, seemingly unaware of the preceding coverage criteria and the fact that ALF staff are prohibited in Massachusetts from rendering hands-on skilled care (including the administration of injectable medications), determined that:

The patient did not require skilled nursing services. The patient had stable insulin requirements requiring routine blood glucose monitoring. He was in an assisted living facility and had caregivers available for administration of his insulin using prefilled syringes. The member was able to direct his insulin dosing based on blood sugar measurements. His caregivers were assisting him with medication administration [at the start of care] and he continued to reside in the assisted living facility during the episode of care.

This decision was made in error insofar as it failed to account for the relevant coverage criteria governing the administration of injectable medications as well as Massachusetts state law requirements.<sup>50</sup> The record supports that S2-7 was unable to administer his own insulin injections and lacked a willing and able caregiver to perform this function.<sup>51</sup> The services provided to this patient therefore met Medicare criteria for coverage.

As another example, the reviewer appeared to be unaware that physical therapy services are covered by Medicare for the purpose of establishing and overseeing a skilled maintenance program. Beneficiary S2-47 was an elderly male whose medical history was significant for Parkinson's disease, congestive heart failure, dementia, coronary artery disease, atrial fibrillation, hypertension, chronic obstructive bronchitis, prostate cancer, and pneumonia. He spent most of his time in his wheelchair due to significant mobility impairments. S2-47 was initially admitted to Excella for rehabilitative therapy following a hospital admission for a fever and an exacerbation of bronchitis. After the initial episode of treatment, the therapist determined that the patient had reached a plateau with treatment. Nevertheless, the therapist concluded that an ongoing maintenance program would be appropriate for S2-47, explaining:

Patient continues to have difficulty with positioning and range of motion, causing patient to sacral sit in [wheelchair] and eventually slide out of [wheelchair]. Patient unable to reposition self in [wheelchair] and caregivers continue to require training in order to assist patient for proper position due to multiple different caregivers at ALF. Patient is awaiting tilt-in-space [wheelchair]. Patient will benefit from continued skilled physical therapy

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<sup>49</sup> MBPM Ch. 7 § 40.1.2.4(A)(2).

<sup>50</sup> This passage is also rife with factual inaccuracies. For example, S2-7's insulin regimen was not "stable" because the dosage was increased immediately prior to the episode under review and then again during the episode secondary to bouts of hyperglycemia. The start of care assessment also does not indicate that the facility staff was assisting S2-7 with his injectable medications; on the contrary, the nurse documented in that note that the staff required assistance and training with this task.

<sup>51</sup> The nurses documented throughout the record that S2-7 could often not remember what he had eaten the previous day, so it is unlikely he would have been able to self-inject his insulin according to the dosages and schedule prescribed by the physician. The patient was also intermittently disoriented; the nurse arrived for one visit at 7 AM, for example, to find S2-7 half-dressed in his room and unsure if it was morning or night.

maintenance program to provide skills of therapist for proper stretching to ensure safe positioning in [wheelchair] to prevent falling out of current [wheelchair] while more appropriate tilt-in-space [wheelchair] is being ordered. The patient's cognitive status and inability to initiate appropriate movement without cuing put the patient at risk for skin breakdown and falling if he is not properly seated in current wheelchair. Skills of the physical therapist are necessary to oversee proper position and ensure hip flexors do not shorten while awaiting fabrication and delivery of new tilt-in-space wheelchair.

The reviewer nonetheless determined that this patient did not require any physical therapy services, simply observing that:

As of [the beginning of the episode in question], the patient had already reached a functional plateau with the skilled physical therapy treatments that had been provided. Therapeutic content had included caregiver education in a home exercise program. Ongoing skilled physical therapy was not indicated after that date.

This decision does not even raise – much less analyze – the fact that S2-47 was recertified for purposes of maintenance therapy. Excella can thus only assume that the reviewer was unaware that the establishment and oversight of a skilled maintenance program constitutes a covered service under the Medicare home health benefit.<sup>52</sup>

In another case, the reviewer decided that skilled nursing services were not medically necessary for a patient throughout the duration of an episode because her condition was allegedly stable. The reviewer wrote:

The patient had skilled nursing needs at the start of care to reconcile her medications and monitor the patient's response to a new living environment. The RN visited the patient eleven times and the patient remained stable and was eating adequately throughout the episode. There was no indication of failing to thrive that was documented. Skilled nursing could have been discontinued after the third visit...

This patient, S2-49, was admitted to home health services following a hospitalization for a UTI, generalized weakness, and a diagnosis of failure to thrive. Her medical history was significant for Parkinson's disease, idiopathic peripheral neuropathy, hypertension, and coronary artery disease. She had recently been placed in the ALF where she resided during the episode under review.

The reviewer's decision, made with the benefit of hindsight, is premised on the notion that S2-49's condition was stable throughout the episode.<sup>53</sup> Even assuming that the reviewer is correct

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<sup>52</sup> Cf. *Jimmo v. Burwell*, 2017 WL 462512, at \*6 (D. Vt. 2017) (directing CMS to publish a statement on its website that includes the following language: “[CMS] reminds the Medicare community of the *Jimmo* Settlement Agreement (January 2014), which clarified that the Medicare program will pay for skilled nursing care and skilled rehabilitation services when a beneficiary needs skilled care in order to maintain function or to prevent or slow decline or deterioration (provided all other coverage criteria are met).”).

<sup>53</sup> These types of retrospective decisions are inappropriate according to Medicare guidelines: “The services must, therefore, be viewed from the perspective of the condition of the patient when the services were ordered and what was, at that time, reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.” MBPM Ch. 7 § 40.1.1.



that the patient was clinically stable (which Excella does not concede), that fact alone is insufficient to deny all remaining skilled nursing services provided to this patient. The MBPM explains:

Where a patient was admitted to home health care for skilled observation because there was a reasonable potential of a complication or a further acute episode, but did not develop a further acute episode or complication, the skilled observation services are still covered for 3 weeks or so long as there remains a reasonable potential for such a complication or further acute episode.<sup>54</sup>

S2-49 was a clinically complex patient who had recently been hospitalized and moved to a new living environment. These facts, in addition to other clinically relevant information documented throughout her record, created a reasonable potential for a complication or acute exacerbation in her condition. Accordingly, the skilled nursing services provided to S2-49 should, at a minimum, be covered for three weeks from her admission to home health services.

The preceding examples suggest that, in many cases, the medical reviewers were unaware of or incorrectly applied various Medicare coverage guidelines governing skilled services. A reasonable review of the relevant documentation will support that, in view of the proper coverage standards, the services provided were medically reasonable and necessary. The OIG must therefore reconsider its decisions that skilled services were not appropriate in 35 of the 70 cases under review.

### **C. Health Insurance Prospective Payment System Coding**

Home health services are reimbursed by Medicare based on the Health Insurance Prospective Payment System (HIPPS) codes submitted with the claim.<sup>55</sup> HIPPS codes represent specific sets of patient characteristics according to which payment determinations are made, and those codes are generated based on the data gathered during comprehensive OASIS assessments. In the home health setting, HIPPS codes are determined in large part by the patient's clinical profile, functional status, and the services to be rendered during the ensuing episode.

In five cases, the reviewers purport to have identified errors in the HIPPS codes used to bill the corresponding claims to Medicare.<sup>56</sup> In every case, the reviewers noted that, "The [coding] discrepancy is related to the clinical severity level [of the HIPPS codes] but cannot be pinpointed further." These discrepancies do not constitute clerical errors on Excella's part but rather oversights by the reviewers.

As noted in section II, all OASIS assessments completed by Excella's clinicians are subject to quality assurance reviews prior to submission of the corresponding claims. In these five cases, the quality reviews resulted in amendments to the OASIS assessment data. These corrections related to OASIS elements such as the order of the diagnoses on the claim, the number and nature of pressure ulcers, and the patient's cognitive abilities, among other things. The assessment

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<sup>54</sup> MBPM Ch. 7 § 40.1.2.1.

<sup>55</sup> See generally Medicare Claims Processing Manual, Ch. 10 (Pub. 100-04, Rev. 3151) (2013).

<sup>56</sup> The reviewers alleged coding discrepancies exist in five cases: S1-17, S1-20, S1-30, S1-41, and S2-42. The Report incorrectly states that such errors were only identified in three cases. See Report at 7, 19-22.

amendments were made by certified OASIS coders in consultation with the treating clinicians and according to CMS policy for amendments to medical records.<sup>57</sup> All of these corrections impacted the clinical domains of the HIPPS codes submitted with the claims. These OASIS corrections are present in the charts, and they were available to the reviewers at the time of the audit. The fact that the reviewers failed to account for information that was clearly available further calls into question the adequacy and thoroughness of the OIG’s audit findings.

**V. THE OIG’S MEDICAL REVIEW CONTRACTOR WAS PREDISPOSED TO FINDING A HIGH ERROR RATE**

The OIG previously confirmed to Excella that ██████████ Federal Services, Inc. (“██████████”) functioned as the medical review contractor in this case. ██████████ is also a longstanding CMS contractor and, among other roles, has served as a Qualified Independent Contractor (QIC) for Medicare Part A fee-for-service claim appeals for more than a decade. From 2005 to 2017, ██████████ was responsible for the Part A East QIC contract, and it held the contract for Part A West appeals from 2008 to 2015.

According to appeals data maintained by CMS, ██████████ issued unfavorable decisions as to the vast majority of Part A claim appeals when it held both QIC contracts. The table below summarizes this data from 2010 to 2015.<sup>58</sup>

<b>Year</b>	<b>Unfavorable Decisions</b>	<b>Partially Favorable Decisions</b>	<b>Fully Favorable Decisions</b>
2010	88.9%	2.9%	8.2%
2011	88.1%	2.2%	9.7%
2012	86.8%	0.7%	12.5%
2013	83.5%	0.4%	14.3%
2014	80.0%	0.9%	19.1%
2015	83.8%	1.6%	14.5%

Among the unfavorable QIC decisions appealed to the Office of Medicare Hearings and Appeals during the same time period, Administrative Law Judges (ALJs) reversed large numbers of these denials in whole or in part.<sup>59</sup>

<b>Year</b>	<b>Unfavorable Decisions</b>	<b>Partially Favorable Decisions</b>	<b>Fully Favorable Decisions</b>
2010	24%	6%	56%
2011	N/A	N/A	N/A
2012	27.9%	6.4%	53.2%

<sup>57</sup> See Medicare Program Integrity Manual (MPIM) Ch. 3 § 3.3.2.5(A)-(B) (Pub. 100-08, Rev. 442) (2012).

<sup>58</sup> CMS, *Second Level of Appeal: Reconsideration by a Qualified Independent Contractor*, Sept. 20, 2017, <https://www.cms.gov/Medicare/Appeals-and-Grievances/OrgMedFFSAppeals/ReconsiderationbyaQualifiedIndependentContractor.html> (last accessed October 3, 2017).

<sup>59</sup> Office of Medicare Hearings and Appeals, *Decision Statistics*, July 17, 2017, <https://www.bhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html> (last accessed October 3, 2017); see also Office of Inspector General, *Improvements are Needed at the Administrative Law Judge Level of Medicare Appeals*, Report No. OEI-02-10-00340, at 9 (2012). This data reflects the dispositions as to all appeals adjudicated by ALJs and is not limited to Part A claims.

2013	25.5%	5.2%	44.3%
2014	30.1%	2.8%	38.7%
2015	37.5%	3.1%	33.6%

In view of [REDACTED] long history of “rubber stamping” claim denials (decisions which were, to a large degree, later reversed by other adjudicators), it is thus unsurprising that the contractor would conclude that 70% of claims from the sample here were incorrectly paid. The audit results in this case are thus not an accurate characterization of Excella’s documentation and billing practices as much as they are a pre-ordained conclusion in search of evidence.<sup>60</sup>

In order to more fully evaluate the OIG’s claim determinations, Excella previously requested copies of the curricula vitae (CVs) of [REDACTED] medical reviewers.<sup>61</sup> To date, the OIG has refused to release this information. This is concerning for a variety of reasons, not least because there would appear to be no legitimate basis for the OIG to withhold the qualifications and credentials of its reviewers. Excella is also troubled because, while the reviewers may be licensed physicians, their determinations do not reflect sufficient familiarity with Medicare coverage requirements for home health services. In the determination summaries, furthermore, the reviewers attested that they were certified coding specialists. Yet, as discussed in section IV.C, the reviewers were apparently unaware that properly-executed amendments to OASIS assessment data affected the HIPPS codes submitted with the claims. As of the date of this submission, Excella still does not possess any background information or details related to the qualifications of the OIG’s reviewers. This absence of transparency is disturbing, unreasonable, and lacking in any legitimate basis.<sup>62</sup>

## **VI. THE OIG’S OVERPAYMENT PROJECTION IS UNRELIABLE AND FLAWED**

Excella has retained the services of a qualified, independent statistician to assess the statistical validity of the OIG’s sampling methodology. In addition to the arguments set forth below, Excella reserves the right to raise any and all issues related to the insufficiency of the OIG’s sample design documentation and the invalidity of its methodology upon completion of the statistician’s review.

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<sup>60</sup> The audit results, on their face, appear to bear this out. For example, the OIG’s statisticians allegedly constructed a stratified random sample in this case whereby claims with payment amounts less than or equal to \$4,500 were allocated to stratum 1 and claims with payment amounts in excess of \$4,500 were assigned to stratum 2. Each stratum was comprised of 50 claims. The medical reviewers identified a 56% error rate for stratum 1 claims and an 84% error rate for stratum 2 claims. Because stratum 2 was populated by claims with higher payment amounts, the higher error rate for those claims purportedly identified by the medical reviewers almost certainly had the effect of increasing the overall alleged overpayment projection.

<sup>61</sup> As part of its request, Excella preemptively agreed to the redaction of all sensitive personal information from the CVs.

<sup>62</sup> Generally Accepted Government Auditing Standards (GAGAS), to which the OIG claims to have adhered in this case, require sufficient competence, expertise, and technical knowledge on the part of auditors and specialists. See Government Accountability Office, *Government Auditing Standards*, Ch. 3 § 3.72, Ch. 6 §§ 6.42 and 6.43 (2011). Due to the OIG’s refusal to release the credentials of its reviewers, there is simply no way for Excella (or any third party) to verify that this requirement has been met here.

**A. The OIG has not identified or followed any set guidelines for its sampling and extrapolation procedures.**

One of the most important components of any audit is the identification of the pertinent laws, rules, regulations, and guidelines that the auditors will use in the conduct of the audit. To this end, GAGAS states that:

Auditors should identify criteria. Criteria represent the laws, regulations, contracts, grant agreements, standards, specific requirements, measures, expected performance, defined business practices, and benchmarks against which performance is compared or evaluated. Criteria identified the required or desired state or expectation with respect to the program or operation. Criteria provide a context for evaluating evidence and understanding the findings, conclusions, and recommendations included in the report. Auditors should use criteria that are relevant to the audit objectives and permit consistent assessment of the subject matter.<sup>63</sup>

The criteria set forth in an audit report are important because they serve as the benchmarks against which the audit results are to be measured. Without such criteria, an independent auditor, reviewer, or even the auditee would be unable to meaningfully assess the results of the audit.<sup>64</sup>

In this case, the Report does not set forth the criteria the OIG followed for the sampling and extrapolation. In related e-mail correspondence between Excella and the OIG, the Agency inquired whether the OIG had followed CMS requirements for statistical sampling.<sup>65</sup> The OIG responded:

No, the OIG is not required to use CMS's statistical sampling criteria. 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*, 2016 U.S. Dist. LEXIS 6816 at \*31-33, 37-39 (W.D. Tex. 2016); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enter., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012). 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 sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

There is no general "legal standard" for the use of extrapolation in audits such as this. All of the cases cited in the above passage apply and analyze CMS requirements for statistical sampling – the very same requirements that the OIG has claimed it did not use here. None of the cited cases stands for the proposition that an extrapolation is always "statistically valid" if the limited steps described by the OIG (e.g., defining the sampling frame and sampling unit, randomly selecting the

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<sup>63</sup> *Id.* at Ch. 6 § 6.37; *see also* Report at 4 ("We conducted this performance audit in accordance with generally accepted government auditing standards.")

<sup>64</sup> *Government Auditing Standards*, Ch. 6 § 6.79.

<sup>65</sup> *See generally* MPIM Ch. 8 § 8.4 *et seq.* (Pub. 100-08, Rev. 377) (2011).

sample, etc.) are followed, nor do those cases define the phrase “statistically valid” outside the context of the Medicare sampling guidelines.

The principal issue presented in each case, moreover, was whether a decision of the Medicare Appeals Council was supported by substantial evidence and correctly applied CMS requirements for statistical sampling.<sup>66</sup> The courts were not asked to establish general legal standards for sampling. In *Balko*, for example, the district and appellate courts were primarily engaged with the issue of whether extrapolation was authorized under the Medicare statute in the first instance.<sup>67</sup> The *Maxmed*, *Anghel*, and *Transyd* cases all address the question of whether concepts such as statistical dependence of sampling units, inadequate precision, insufficient sample size, or unrepresentativeness of the sample are sufficient bases to invalidate an extrapolation pursuant to CMS rules.<sup>68</sup> The cases are useless for the purpose of establishing general requirements for statistical sampling. The OIG’s failure to identify the criteria according to which it designed its sampling plan and projected the alleged overpayment identified in the audit prejudices Excella and casts into doubt the adequacy and accuracy of the OIG’s estimated overpayment.

**B. The OIG has refused to furnish Excella with complete information related to its sampling methodology.**

As with the OIG’s refusal to disclose the credentials of its medical reviewers, the OIG has demonstrated a further lack of transparency by refusing to produce complete information related to its sampling methodology. Following a request from Excella, the OIG provided sampling materials that included, but were not limited to, the following: a copy of the sampling plan, the sampling frame, a list of the random numbers used to select the sample, and the RAT-STATS output from the extrapolation process. The data delivered to Excella did not include the universe file from which the sampling frame was created. The OIG, in response to a subsequent request from Excella, declined to produce the universe. Without the universe file, Excella’s statistician may not be able to perform a complete analysis of the OIG’s sampling methodology. This will further impede Excella’s ability to meaningfully contest the alleged overpayment determination through the CMS appeals process.

## VII. CONCLUSION

As discussed herein, the OIG’s claim determinations are flawed in that they did not properly apply Medicare coverage guidelines for home health services or take into account the individualized clinical needs of the beneficiaries. The medical reviewers applied the incorrect homebound criteria for claims with dates of service prior to November 2013, and it is readily

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<sup>66</sup> Courts charged with reviewing final agency decisions, such as those issued by the Medicare Appeals Council, are required to extend significant deference to the agency’s factual findings and legal interpretations of its own regulations. See, e.g., *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d. 619, 624-25 (W.D. Tex. 2016).

<sup>67</sup> See, e.g., *John Balko & Assocs. v. Sebelius*, 2012 WL 6738246, at \*18-26 (W.D. Pa. 2012). The OIG also vaguely references a portion of the district court’s opinion in *Balko* regarding precision. As used in the context of sampling, precision is not a synonym for statistical validity but instead pertains to the width of the confidence interval relative to the point estimate.

<sup>68</sup> *Maxmed*, 152 F. Supp. 3d. at 634-47; *Anghel v. Sebelius*, 912 F. Supp. 2d. 4, 16-22 (E.D.N.Y. 2012); *Transyd Enters. LLC v. Sebelius*, 2012 WL 1067561, at \*22-31 (S.D. Tex. 2012).

apparent from the claim decisions that the reviewers impermissibly used ambulation distance as a “rule of thumb” for establishing beneficiary homebound status. The reviewers have also improperly denied therapy services in several instances simply because the beneficiaries were ALF residents and appeared unaware of specific Medicare coverage criteria in other cases. For these reasons, the OIG should reconsider its findings that Excella was allegedly overpaid by Medicare in connection with any of the sample claims.

Excella is committed to providing only the highest quality home health services to its patients while maintaining strict compliance with all applicable laws rules and regulations. Agencies like Excella play a vital role in our nation’s healthcare system in that they enable elderly patients to reside as safely and independently as possible in their own homes. This enhances patient quality of life and also consistently reduces the need for utilization of more costly healthcare services.

Although Excella intends to vigorously contest the findings summarized in the Report through the CMS administrative appeals process, the Agency nonetheless appreciates the opportunity to comment on the OIG’s findings before the Report is finalized. Excella would also like to extend its gratitude to the OIG auditors for their professionalism and prompt responses to the Agency’s inquiries and requests for additional information during the audit process.

Respectfully Submitted,

  
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