October 26, 2018

Ms. Susan Edwards  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-0803-N  
Room 5513  
Cohen Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Submitted electronically to www.regulations.gov

Re: Comments on OIG-0803-N, “Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP.”

Dear Inspector General Edwards:

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Office of Inspector General’s (OIG’s) above captioned Request for Information (Request). AAHomecare members include a cross section of suppliers, manufacturers, and other industry stakeholders that assist, make or furnish Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) that Medicare beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services. As such, our comments are primarily focused on the Request as it pertains to DMEPOS.

Importance of Coordination of Care

AAHomecare agrees with the OIG that providers and suppliers need to be encouraged to coordinate with each other in providing care to patients covered by federal government health care programs. DME suppliers are central to such coordination furnishing equipment and products designed to allow patients to live independently in their homes (as opposed to living in more expensive facilities) and reduce the incidences of physician and hospital visits. Unlike most other providers, DME suppliers have regular communications with patients and their caregivers.
These communications allow DME suppliers to report to, and coordinate with, treating physicians and other clinicians.

Providers that should collaborate include hospitals, physicians, therapists (respiratory, physical and occupational), DME suppliers, home health agencies, pharmacies, labs and skilled nursing facilities. When such collaboration occurs, patients are treated more cost effectively, patients avoid unnecessary physician and hospital visits, and patients save money.

Coordination of Care and its Relationship to Preventing Fraud

When providers and suppliers work together in delivering patient care, challenges arise. Specifically, any time one provider refers a patient to another provider and there is a payment of compensation or sharing of reimbursement, then there is a risk of a kickback in violation of the federal anti-kickback statute (AKS).1 Likewise, any time a provider works with and/or incentivizes a patient with the goal of improving the patient’s health, then there is a risk of an inducement in violation of the beneficiary inducement statute (Inducement Statute).2 And yet, referrals, sharing of compensation, and incentivizing patients are necessary for there to be effective coordination of care. While it is important to encourage coordination, it is equally important that protection against fraud be maintained.

Impact of the AKS on Care Coordination

The AKS is designed to prevent a person or entity from receiving anything of value in exchange for referring (or arranging for the referral of) a patient. The AKS has a number of safe harbors. A safe harbor is designed to permit an arrangement that will enhance treatment of a patient but that, without the safe harbor, may violate the AKS. While the existing safe harbors have served patients well, they are proving to be inadequate as health care moves to a coordination of care model (New Model). As such, AAHomecare supports the goal of modifying and expanding the AKS safe harbors to facilitate coordination of care.

Impact of the Inducement Statute on Care Coordination

The Inducement Statute is designed to prevent a provider from offering anything of value to a patient in order to induce the patient to purchase a good or service from the provider or supplier. The nominal value exception to the Inducement Statute allows a provider or supplier to give a gift of “nominal value” to the patient.3 Currently, a provider can offer one gift that has a retail value of $15 or less.4 The provider can offer multiple gifts to a patient so long as the gifts, in the aggregate, do not exceed $75 in retail value over a 12 month period.5 These gifts cannot be in

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1 42 U.S.C. § 1320a-7b(b).
2 42 U.S.C. § 1320a-7a(a)(5).
3 Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting from Public Law 104-191, 65 FR 24410, 24411 (Apr. 26, 2000).
5 Id.
the form of money or money equivalents (such as gift cards). While the existing nominal value exception has served patients well, it is proving to be inadequate as health care moves to the New Model. As such, AAHomecare supports the goal of modifying and expanding the nominal value exception to facilitate coordination of care.

**New Safe Harbor for Collection of Copayments**

A provider/supplier is required to make a reasonable effort to collect copayments from patients. “Reasonable effort” is not defined. However, in a Fraud Alert and in Advisory Opinions, the Office of Inspector General (OIG) has set out guidance for providers to follow when collecting copayments. The OIG advises providers not to advertise in advance that if the patient can show a financial inability to pay the copayment, then the provider might waive or reduce the copayment. Making such an alternative available before the patient decides to obtain services from the provider will likely be construed as an inducement in violation of the Inducement Statute and a kickback in violation of the AKS. The OIG suggests that when the provider provides services/products, the provider should explain to the patient that he/she is obligated to pay the copayment. Only when the patient expresses an inability to pay the copayment can the provider explain that the copayment might be waived or reduced if the patient can show an inability to pay.

This course of action can result in patients not seeking medical care from physicians, DME suppliers and other health care providers thereby resulting in more expensive hospitalization as the patient’s health deteriorates. This course of action also thrusts uncertainty on providers. The unknown issues for the provider include: (i) what constitutes a “reasonable effort” to convince a patient to pay his/her copayment; and (ii) what kind of information must the patient submit to the provider to justify a waiver or reduction of the copayment?

AAHomecare suggests that a new OIG safe harbor be published that addresses a provider or supplier disclosing in advance (before the patient decides to obtain services and/or a product from the provider) when the provider will waive or reduce the patient’s copayment obligation. AAHomecare suggests that providers and suppliers be allowed to disclose to patients in advance, that if a patient’s income is at or below 300% of the Federal Poverty Guidelines (FPG), then the patient’s copayment obligation will automatically be waived and if a patient’s income is greater than 300% of the FPG, then the provider will gather financial information from the patient and then decide as to whether the provider will waive or reduce the copayment. The financial information gathered will include expenses of the patient and the number of dependents who are wholly or partially dependent on the patient.

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11 Id.
12 Id.
If patients know that waiver or reduction of the copayment is available to them if certain metrics are met, then the patients will likely be more inclined to seek services and products before their health deteriorates to the point that hospitalization is required.

Modification to Personal Services and Management Contracts (PSMC) Safe Harbor to the AKS

The PSMC safe harbor states that if the elements set out in the safe harbor are met, then payment by a provider to a person/entity (in the position to generate referrals to the provider) for services is protected from liability under the AKS. For example, assume that (i) a physician refers patients to a DME supplier, (ii) the physician also provides substantive services to the DME supplier, and (iii) the DME supplier pays the physician for his/her services. According to the PSMC safe harbor, the compensation paid by the provider for the services must be fixed one year in advance, be fair market value (FMV), and cannot consider the anticipated volume of business between the parties.

The challenge is that it is almost impossible for the provider and the other party (e.g., physician) to establish a fixed annual fee without considering the anticipated volume of business between them. By contrast, the Personal Services exception to Stark allows a provider to pay a physician on a “per service” basis. While the total payments to the physician for the year will vary based on the business between the physician and provider/supplier, the physician is only paid for the actual services that he/she renders. In addition, the compensation must be FMV. The compensation methodology in the Personal Services exception to Stark is more practical than the compensation methodology in the PSMC safe harbor.

AAHomecare suggests that the PSMC safe harbor be modified so that it is consistent with the Personal Services exception to Stark. That is, under the PSMC safe harbor, instead of the compensation having to be fixed one year in advance, the compensation can be calculated on a “per service” basis. While doing so will result in the compensation to the referral source varying based on the volume of business generated between the parties, risk to the Medicare program will be minimal so long as the compensation is for legitimate services and is the FMV equivalent of the services provided by the referral source to the provider.

Changing the compensation methodology from a fixed annual fee to “per service” compensation will enhance coordination of care and improve patient outcomes. Home health agencies, DME suppliers, pharmacies, therapy clinics and other providers will be more inclined to work with physicians, hospitals and other referral sources to benefit patients. Specifically, providers will be more comfortable in paying referral sources for legitimate services that will improve the chances of positive patient outcomes.

New Non-Monetary Compensation Safe Harbor

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13 42 C.F.R. § 1001.952(d).
14 Id. at (4)-(5).
15 42 C.F.R. § 411.357(d).
16 Id. at (1)(v).
The Stark non-monetary compensation exception allows a provider/supplier to spend up to a certain dollar amount each calendar year on a physician.\textsuperscript{17} For 2018, the dollar amount is $407.\textsuperscript{18} This amount will increase each year in accordance with inflation. The expenditures cannot be cash or cash equivalents such as gift cards.\textsuperscript{19} The expenditures can be for educational lunches/dinners and for social activities. Because the dollar amount is low, expenditure of this dollar amount should not affect the physician’s independent clinical judgment. From a practical standpoint, if the physician and the provider become familiar (and comfortable) with each other, then it will be easier for them to work together to enhance treatment of patients.

With the above in mind, AAHomecare suggests that the OIG adopt a safe harbor that mirrors the Stark non-monetary compensation exception. Doing so will memorialize what Stark already allows. Doing so will also remove the conflict between the AKS and Stark - that is - in spending up to a certain dollar amount each calendar year on a physician, the provider will comply with Stark but is at risk of violating the AKS. Adopting a non-monetary compensation safe harbor will eliminate this unnecessary risk under the AKS.

It is also important that a provider/supplier have as good of a relationship with a physician’s staff as it is for the provider to have a good relationship with the physician. The physician’s staff play an integral role in the provision of health care to patients. Because there is currently no non-monetary compensation safe harbor/exception for the physician’s staff, any money spent on behalf of the staff (e.g. educational lunches) possibly implicate the AKS. In order to eliminate this uncertainty, AAHomecare suggests that the new non-monetary compensation safe harbor be adopted that includes expenditures on behalf of the physician’s staff.

\textbf{Modification to Small Investment Interest Safe Harbor - Relaxation of the Two \textit{“60 - 40 Tests”}}

A “joint venture” arises when two or more people/entities own something together. A joint venture can be elaborate or simple. There are a number of opportunities for providers/suppliers to form joint ventures that will combine skill sets for the benefit of patients.

However, there is hesitation on the part of providers and suppliers to do so. This is because if one joint venturer is a referral source to the other joint venturer, which is often the case, then there is a concern that the joint venture will be construed as a prohibited kickback under the AKS. An improperly structured joint venture can result in a kickback if the arrangement is a “sweetheart deal” for the joint venturer that is a referral source to the other joint venturer.

The Small Investment Interest safe harbor is inadequate to provide safety to joint ventures. This is because of the two 60 - 40 tests set out in the safe harbor. These two tests state that in order for the joint venture to meet the terms of the safe harbor, then (i) not more than 40% of the joint venture can be owned by a party that is in the position to refer to, or transact business with, the joint venture, and (ii) not more than 40% of the business generated by the joint venture can come

\textsuperscript{17} 42 C.F.R. § 411.357(k).
\textsuperscript{18} CENTERS FOR MEDICARE & MEDICAID SERVICES, CPI-U Updates (Nov. 16, 2017), \url{https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html}.
\textsuperscript{19} 42 C.F.R. § 411.357(k)(1).
from one of the parties to the joint venture. When one of the parties to the joint venture is a referral source, it is virtually impossible to comply with the two 60 - 40 tests.

Not complying with the safe harbor does not mean that the joint venture violates the AKS. Rather, it means that a more in-depth analysis needs to be conducted under other OIG guidance and case law. Besides Advisory Opinions that might exist, the only OIG guidance are (i) the 1989 Special Fraud Alert entitled “Joint Ventures” and (ii) the April 2003 Special Advisory Bulletin (“Contractual Joint Ventures”). While the Fraud Alert and Special Advisory Bulletin are detailed and helpful, they nevertheless result in ambiguity as to when a joint venture is proper and when it is improper.

Accordingly, AAHomecare suggests that the two “60 - 40 test” be removed from the safe harbor and in their place, the OIG set out clear guidelines (consistent with the Special Fraud Alert and Special Advisory Bulletin) that govern when a joint venture falls within the Small Investment Interest safe harbor.

Properly structured joint ventures should be encouraged by the OIG and CMS. Examples include (i) a DME supplier jointly owned by a hospital and an existing DME supplier and (ii) a pharmacy jointly owned by a physician and an existing pharmacy. Joint ventures, such as these, will result in coordination of care for beneficiaries. For example, the DME joint venture (owned by the hospital and the independent DME supplier) can have a “hands on” approach with patients who are discharged from the hospital. The joint venture DME supplier can coordinate with the patient, and his/her caregivers and physician, with the goal of the patient (i) taking his/her medications as prescribed, (ii) making scheduled physician office appointments, and (iii) eating well and hydrating. These simple steps will decrease the risk of the patient being readmitted to the hospital soon after discharge.

New Preferred Provider Safe Harbor

Under the Hospital Readmission Reduction Program, if a patient is treated at a hospital for a specifically enumerated disease (e.g., chronic obstructive pulmonary disease [COPD], congestive heart failure, or pneumonia) and then if the patient is readmitted soon after discharge (normally 30 days) for the same disease, then the hospital will realize a reduction in Medicare reimbursement during the next calendar year. For this and other reasons, hospitals are focused on the health of their patients following discharge.

Increasingly, hospitals and other providers (DME suppliers, pharmacies, home health agencies, etc.) are entering into preferred provider arrangements (PPAs) along the following lines:

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20 42 C.F.R. § 1001.952(a)(2)(i), (vi).
21 See U.S. Dep’t Health and Human Serv., Office of Inspector General, Publication of OIG Special Fraud Alerts, 59 FR 65372 (December 19, 1994). The Special Fraud Alert is also available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.
23 42 U.S.C. § 1395ww(q); 42 C.F.R. § 412.154.
If a physician orders a post-discharge service or product for the patient, then the hospital will offer freedom of choice (i.e., the patient can choose his/her post-discharge provider of services and products). If the patient does not express a preference, then the hospital can recommend the hospital’s “preferred provider.”

In return for being designated as the preferred provider, the ancillary provider commits to providing value-added services and products for the patient with the goal being to keep the patient healthy so that he/she is not readmitted soon after discharge.

The provider’s services may include calling the patient and his/her caregiver to remind them (i) of an upcoming physician’s appointment; (ii) that the patient needs to take his/her prescription drugs; and (iii) that the patient needs to eat regular healthy meals and to hydrate.

These value-added services do not result in a direct financial benefit to the hospital and these services can be categorized as additional value-added services that an innovative provider should provide in the normal course and scope of its business. Nevertheless, there is a risk that such value-added services by the provider will be construed as “something of value” to a referral source, thereby implicating the AKS.

A preferred provider arrangement between a hospital and a provider is a clear example of how coordination of care should be implemented: the hospital “hands off” the patient to the provider upon discharge and the provider then works with the patient and his/her caregiver with the goal of keeping the patient healthy.

AAHomecare suggests that the OIG publish a safe harbor that gives protection to these types of preferred provider arrangements. Such a safe harbor should not be limited to relationships between providers and hospitals. The safe harbor should be broad enough to encompass similar preferred provider arrangements between ancillary providers on the one hand and physicians, wound care centers, skilled nursing facilities (SNFs) and similarly-situated providers on the other hand.

Modification to Electronic Health Records (EHR) Safe Harbor

The EHR safe harbor provides kickback protection to arrangements in which a provider (e.g., pharmacy) furnishes software to a long term care facility (facility) that enables the facility to implement an EHR system. In order for the provider and facility to avail themselves of this safe harbor, a number of requirements must be met, the most important of which is interoperability.

Interoperability means that the facility can utilize the EHR for multiple purposes; such use is not limited to the relationship between the facility and the provider that

24 42 C.F.R. 411.357(y).
25 Id. at (2).
furnishes the software. Another important element is that the facility must pay at least 15% of the cost of the software.

While the provision of EHR software is “something of value” to a referral source, which normally would implicate the AKS, the OIG acknowledges the importance of facilities moving from hard copy documents to electronic records. The elements of the safe harbor are designed to reduce the risk that the donation of the software results in a prohibited kickback.

AAHomecare suggests that the EHR safe harbor be expanded to cover other contributions of products and services to referral sources in which such products/services enhance coordination of care and patient outcomes. Specifically, AAHomecare suggests that the safe harbor be expanded to include the following:

- Contributions of EHR software to providers other than facilities, such as rural hospitals, rural health clinics, physician offices, physical/occupational therapy clinics, behavioral health clinics, SNFs, hospices, wound care centers, and assisted living facilities.
- Contributions of other types of technology such as computers, tablets, video conferencing capabilities, and diagnostic equipment.

As a result of such contributions, health care providers will share the cost of technology that will, in turn, contribute to care coordination and better patient outcomes.

Consistency Among the AKS, Stark and Inducement Statute

There are inconsistencies among the AKS, Stark and the Inducement Statute. For example:

- Stark allows a provider to spend a certain dollar amount each year on non-cash/non-cash equivalent items for a physician. In 2018, this amount is $407. However, there is not a similar exception or safe harbor under the AKS. Technically, if a provider spends e.g., $395 on a physician in 2018, then while the provider will not violate Stark there is a risk that the provider will be construed to violate the AKS.

- The Stark Personal Services exception allows a provider to pay a physician on a “per service” basis so long as the payments are FMV. On the other hand, the Personal Services and Management Contracts safe harbor to the AKS requires payments to a physician for services to be set one year in advance (e.g., $12,000 over the next 12

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26 Id. at Note to Paragraph (“[I]nteroperable shall mean able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings[,]”).
27 42 C.F.R. § 411.357(y)(11).
28 See generally U.S. Dep’t of Health & Human Serv., Office of Inspector General, Advisory Opinion No. 14-03 (Apr. 1, 2014) (“The OIG believes that the efficient exchange of health information between health care providers, practitioners, and suppliers is a laudable goal.”).
29 42 C.F.R. § 411.357(k).
31 42 C.F.R. § 411.357(d).
months, or $1000 per month). Technically, if a provider pays a physician on a “per service” basis, then while the provider will not violate Stark there is a risk that the provider will be construed to violate the AKS.

- The “nominal value” exception to the Inducement Statute allows a provider to provide minimally valued gifts to beneficiaries ($15 retail value per gift and $75 in the aggregate over 12 months). However, there is not a similar exception or safe harbor to the AKS. Technically, if a provider provides gifts to beneficiaries in accordance with the nominal value exception, then there is nevertheless a risk that the provider will be construed to violate the AKS.

AAHomecare suggests that the OIG issue a fraud alert that states that if an arrangement is acceptable under one of these three statutes, but if the arrangement might nevertheless technically violate one of the other two statutes, the OIG will not bring an enforcement action on the basis of violation of the other statute.

Sincerely,

Kimberley S. Brummett, MBA
Vice President, Regulatory Affairs

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32 42 C.F.R. § 1001.952(d)(4)-(5).
October 10, 2018

A. Nicole Clowers  
U.S. Government Accountability Office  
441 G St., NW  
Washington, DC 20548  
clowersa@gao.gov

Dear Ms. Clowers:

As the national association for DMEPOS suppliers, manufacturers, and other industry stakeholders, the American Association for Homecare (AAHomecare) would like to submit our response to the Government Accountability Office (GAO) report, “Medicare Fee-For-Service; Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment,” examined potential effects of the reduced rates for DME in non-competitive bid areas (non-CBAs) that took effect January 1, 2016. The Centers for Medicare and Medicaid Services (CMS) is required to use information from the DME competitive bidding program to adjust Medicare fee-for-service rates for DME items included in the bid program, in areas that are not part of the bid program, starting January 1, 2016. CMS simply used the bid program rates and applied them to the remaining areas of the country, despite there being no limited number of contractors with an ensuing expected increase in volume.

Following are GAO findings, and AAHomecare’s responses:

1. FFS payment Rate Reductions Were Generally Significant

AAHomecare: We agree.

The competitive bid program has produced unsustainably low rates, due to a flawed bid system. CMS has acknowledged these flaws in two recent rules. In its May 11, 2018 interim final rule (IFR), CMS acknowledged that the extremely low bid rates that were used to set rates in rural areas of the country have produced access issues. As a result, CMS raised rates in these areas

2 Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and on-Contiguous Areas, 83 Fed. Reg 21912 (May 11, 2018).
from June 1 through December 31, 2018. In its proposed rule issued July 19, 2018, CMS has proposed to continue those increased rates in rural areas through 2019 and 2020. CMS has also proposed to reform the bid program rate calculation methodology that would increase bid rates. Specifically, CMS is proposing to use the “maximum winning bid” to set the bid rates, instead of the current “median bid” methodology. CMS explained that the current method will result in a financially unsustainable program, that will cause access issues.

2. The Number of DME Suppliers in Non-Bid Areas Continued a Trend of Annual Decreases

AAHomecare: We agree.

AAHomecare analysis confirms that there have been a significant number of DME supplier closures in all non-CBAs, those that are rural and non-contiguous, and those that are not. CMS has also identified a decrease in the number of DME suppliers and has raised the issue that this could present access problems. In its May 11, 2018 IFR, CMS stated that the number of suppliers serving non-CBAs is steadily abating, and that CMS does not know whether the remaining suppliers “will have the financial ability to continue expanding their businesses to continue to satisfy market demand.” Based on an analysis of CMS data, AAHomecare has identified a significant number of supplier location closures in all non-CBAs. From 2010 to 2018, 31 percent of locations in rural areas have closed, and 33 percent of non-rural (non-CBA) supplier locations have closed. The very same beneficiary access and supplier viability issues that CMS has identified in the rural and non-contiguous areas also exist in the remaining non-CBAs. As CMS has acknowledged, a financially viable DME supplier market is necessary because “reduced access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays.”

3. Available evidence indicates no widespread access issues in the first year of reduced DME payment rates in non-bid areas

AAHomecare: We disagree, and CMS has also raised the issue that access issues may be arising due to the number of DME supplier closures.

In its May 11, 2018 IFR, CMS recognized that the decreasing number of DME suppliers could present real issues for beneficiary access. In that IFR, CMS expressed its concern that the reduced number of suppliers will have “the financial ability to continue expanding their businesses to continue to satisfy market demand.” CMS continued, “We recognize that reduced

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3 AAHomecare analysis of CMS data obtained via a FOIA request to the Pricing, Data Analysis and Coding (PDAC) contractor; analysis of number of DME suppliers who provide hospital beds, wheelchairs, oxygen, RAD, CPAP, support surfaces, NPWT, ostomy, urological, and enteral nutrition items and services.


5 AAHomecare analysis of 2010-2018 Medicare NPI data obtained from CMS via FOIA requests; it includes suppliers providing the following product categories: hospital beds, wheelchairs (complex and standard), oxygen, RAD, CPAP, support surfaces, NPWT, ostomy items, urologicals, and enteral nutrition.


7 Id.

8 Id.
access to DME may put beneficiaries at risk of poor health outcomes or increase the length of hospital stays." As a result of its findings, CMS raised the payment rates in non-rural and non-contiguous areas of the country from June 1 through December 31, 2018 to address its access concerns. In its proposed rule issued July 19, 2018, CMS echoed those concerns and proposed to continue those higher payment rates through 2020. These CMS policy initiatives clearly illustrate the existence of access issues resulting from the reduced payment rates in non-CBAs.

Several recent studies illustrate the DME supplier viability and associated access issues that exist across the country, in both bid areas and non-CBAs. A November 2017 study by Dobson DaVanzo & Associates, “Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences,” found that beneficiaries and case managers have reported adverse changes to access and availability to oxygen therapy and DME and supplies since July 1, 2016. Beneficiaries self-reported intentionally bypassing the Medicare DME benefit they are entitled to and are instead paying for equipment and supplies out-of-pocket to avoid delays and inaccessible equipment. Those reports were corroborated by case managers’ reports on beneficiary complaints.

A more recent Dobson DaVanzo & Associates report focused on issues in non-rural non-CBAs. This August 15, 2018 study, “Beneficiary Access to DME at National Level as compared to Beneficiary Access in Non-Rural-Non-Bid Areas,” found results in this subset area to be similar to the results reported in its November 2017 report. In these non-rural non-CBAs, Dobson DaVanzo found widespread dissatisfaction by beneficiaries and case managers, indicating market failures: access and availability, increased readmissions, delays of medically necessary equipment and increased out-of-pocket expenses. More specifically, between 41 and 83 percent of beneficiaries reported some level of access issues in obtaining medically necessary DME items in all product categories, 46 percent of beneficiaries reported delays in receiving their items, and 48 percent of beneficiaries reported increased out-of-pocket medical costs for their DME and supplies. Ninety two percent of case managers in non-rural non-CBAs reported delays in hospital discharges or a delay in the HME and/or supplies. Sixty-five percent of case managers reported beneficiary complications, emergency care, or readmissions due to issues with HME.

The California Hospital Association (CHA) has identified the fact that California hospitals and post-acute providers have reported significant delays in being able to obtain timely delivery of DME.

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9 Id.
10 Medicare Program; ESRD PPS, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, ESRD Quality Incentive Program, DMEPOS Competitive Bidding Program and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS, 83 Fed. Reg. 34304 (July 19, 2018)
12 Id.
13 Id.
14 Id.
15 Id.
16 Id.
for patients to ensure safe discharge from the hospital or other post-acute care settings. CHA also found that these access issues are occurring in both CBAs and non-CBAs, and documented these access issues in their comments to CMS submitted in response to CMS’ July 19, 2018 proposed rule. CHA noted that California hospitals and post-acute care providers report significant difficulties in obtaining timely delivery of medically necessary DME for Medicare beneficiaries upon hospital discharge, and that since CMS implemented the CBP, this issue has become increasingly acute.

The American Thoracic Society (ATS) published a peer reviewed study on October 19, 2017, “Patient Perception of the Adequacy of Supplemental Oxygen Therapy: Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey,” (ATS Study) which found that 50 percent of all respondents reporting having “problems” accessing oxygen. The ATS Study concluded that systemic problems exist within the DME industry concerning oxygen therapy that significantly and negatively affect non-Medicare and Medicare beneficiaries’ ability to access necessary and quality items to facilitate their lifestyles.

Members of Congress have heard extensive reports around the country regarding access problems caused by the low payment rates, both in and out of CBAs. As a result, there are currently 156 U.S. Representatives who have co-sponsored H.R. 4229, a bill that would provide payment relief to DME suppliers serving beneficiaries in all non-CBAs, not just those that are in rural and non-contiguous areas. Further, in its FY 2018 Budget Appropriations law, Congress included Conference Report language urging the Administration to implement this IFR, as a measure to address some of the apparent problems resulting from the low payment rates.

In response to CMS’ May 11, 2018 IFR, the Congressional delegation representing the state of West Virginia sent CMS a letter expressing its serious concerns that the payment relief in the IFR did “not go far enough to ensure continued access for the elderly and disabled who rely on this equipment and those who service it.” The Congressional delegation explained how West Virginia has lost 38 percent of its providers in the last two years, and that it has repeatedly expressed its concerns to CMS about the higher costs that providers in West Virginia incur relative to their urban counterparts. Importantly, the delegation explained that CMS’ definition of “rural” does not comport with the reality of West Virginia where many areas it considers “rural” CMS does not.

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19 Id.


All these reports, which come from beneficiaries, caregivers, hospitals and other providers, as well as from federal policy makers, clearly demonstrate the extensive and serious access issues beneficiaries are facing across the country. The problems stem from the dramatic reductions in payment rates and the number of DME suppliers available to provide medically necessary DMEPOS items to beneficiaries.

4. The Percentage of Medicare Enrolled Participating Suppliers and Rates of Assignment for Rate-Adjusted Items Did Not Change Following the Implementation of Adjusted Rates

AAHomecare: We agree but note that these are not good indicators of access issues.

There are a number of hurdles that make it very challenging or prohibitive for suppliers to change their practices and file claims on a non-assigned basis:

- **Prohibition on filing non-assigned claims for dual eligible beneficiaries**: The Social Security Act requires suppliers who serve beneficiaries with both Medicare and Medicaid (“dual eligibles”) to accept assignment. These beneficiaries account for about 20 percent of all Medicare beneficiaries. CMS also states that dual eligibles “account for a disproportionately large share of expenditures in both the Medicare and Medicaid programs,” amplifying that number well beyond 1 in 5.

- **Limited opportunities to switch from participating to non-participating supplier**: A supplier is bound to its current status for the full calendar year. To become a non-participating supplier, the supplier must notify the National Supplier Clearinghouse in writing during the supplier agreement enrollment period, generally mid-November to late December. The change does not take effect until January 1 of the following year.

- **Inadequate CMS guidance on filing non-assigned claims**: There is limited CMS guidance on the procedures for filing non-assigned claims, and without greater education, suppliers are unable to determine if they are at risk for audits and recoupment regarding issues like defining “excess” and “customary charges,” filing assigned and non-assigned claims on the same day.

- **Risk of non-payment by beneficiaries for capped rental items**: For capped rental items, the supplier directly collects payment from the beneficiary monthly and must get the beneficiary to sign a Signature Authorization Form each month. This process creates additional workloads for the supplier and can be confusing to beneficiaries.

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24 SSA, Section 1848(g)(3)(A)
• **Specific Supplier Communications must be made to Medicare beneficiaries in advance of changes:** A supplier is required to notify current beneficiaries no less than 30 days prior to changing its assignment practices and/or the products offered on an assigned basis.

AAHomecare appreciates the opportunity to provide feedback on this important study. As stated above, there are many areas within the GAO’s findings on access and utilization of DME items that does not reflect what the industry, other stakeholders, and independent studies have reported. We look forward to further discussions on this issue. Please feel free to contact me if I can answer any questions about our comments above.

Sincerely,

Kimberley S. Brummett
Vice President of Regulatory Affairs
American Association for Homecare