Submitted 11/4/22 via Form on CMS' Website: https://www.cms.gov/request-information-make-your-voice-heard

1a. CMS wants to empower all individuals to efficiently navigate the healthcare system and access comprehensive healthcare. We are interested in receiving public comment on personal perspectives and experiences, including narrative anecdotes, describing challenges individuals currently face in understanding, choosing, accessing, paying for, or utilizing healthcare services (including medication) across CMS programs.

Examples may include, but are not limited to:

- Challenges accessing comprehensive and timely healthcare services and medication, including primary care, long-term care, home and community-based services, mental health and substance use disorder services;
- Challenges in accessing care in underserved areas, including rural areas;
- Receiving culturally and linguistically appropriate care (e.g., tailoring services to an individual's culture and language preferences);
- Challenges with health plan enrollment;
- Challenges of accessing reproductive health services;
- Challenges of accessing maternal health services;
- Challenges of accessing oral health services and the impact on overall health;
- Understanding coverage options, and/or technology to support access to coverage; and,
- Perspectives on how CMS can better communicate quality standards and accessibility information to individuals, particularly those with social risk factors.

AAH Response:

AAH will not respond. The question is for consumer/beneficiary groups to answer.

1b. Recommendations for how CMS can address these challenges through our policies and programs.

AAH Response:

AAH will not respond. The question is for consumer/beneficiary groups to answer.

2a . CMS wants to better understand the factors impacting provider well-being and learn more about the distribution of the healthcare workforce. We are particularly interested in understanding the greatest challenges for healthcare workers in meeting the needs of their patients, and the impact of CMS policies, documentation and reporting requirements, operations, or communications on provider well-being and retention.

Examples may include, but are not limited to:

- Key factors that impact provider well-being and experiences of strained healthcare workers (e.g., compassion fatigue, retention, maldistribution);
- The increasing use of digital health technology on provider well-being and attrition;
- Feedback regarding compliance with payment policies and quality programs, such as provider enrollment requirements on healthcare worker participation in underserved populations, and what improvements can be made;
- Impact of CMS policies on patient panel selection, and on providers' ability to serve various populations; and
- Factors that influence providers' willingness or ability to serve certain populations, particularly those that are underserved and individuals dually eligible for Medicare and Medicaid.

AAH Response:

DMEPOS suppliers face many additional costs over and above the cost of acquiring equipment. There are indirect costs such as intensive education and follow-up with patients, delivery, compliance, staff training, and documentation retrieval from clinical records. During the public health emergency (PHE), suppliers have experienced increased acquisition and shipping costs, delays in supply chain, and difficulty obtaining personal protective equipment (PPE). For certain equipment and supplies, such as intermittent catheters, case management of patients and education are a large component of the cost. In addition to the standard customer service, some suppliers have established bi-lingual case management programs that include welcome calls, lifestyle education materials, and check-in calls every 30-60 days to encourage access to educational materials at critical times. Supplier customer service representatives must be specifically trained for complex product categories to help patients. There is no separate billing code for the specific education suppliers provide. New patients often need to try different types of medical supplies or equipment before they find the right product that meets their needs. This trial-and-error process is time and resource consuming for suppliers.

With static Medicare payment rates and high operational costs, it is difficult for suppliers to continue to operate and extend services beyond their limited capacity. Overall, there has been a 30% decrease in the number of DMEPOS suppliers since competitive bidding was implemented nationally. Since bids were submitted in 2015, a $100 DME item then under the unadjusted fee schedule is now equivalent to $124 due to inflation. However, due to the implementation of two rounds of the DMEPOS competitive bidding program in 2016 and 2017, where suppliers saw on average a 7% decrease in their rates, reimbursement in competitive bidding areas has only been adjusted to the equivalent of $101 today. Although suppliers try their best to service all patients that are in need, even providing services at a financial loss, the financial constraints have limited the supplier's ability to service all patients.

2b. Recommendations for CMS policy and program initiatives that could support provider well-being and increase provider willingness to serve certain populations.

AAH Response:

The COVID-19 pandemic has exacerbated acquisition and operational cost challenges for DME suppliers, as it has for many other industries. However, DMEPOS suppliers are constrained under pre-determined, set fee schedules that fail to factor in the increased costs of providing care. This has resulted in an unsustainable reimbursement environment that jeopardizes patient access to care and threatens the financial viability of the DMEPOS industry in meeting their communities' needs.

Costs have continued to rise throughout the pandemic. The entire supply chain has been affected while demand climbs on key product categories used to treat COVID-19 globally such as oxygen and ventilators as well as non-direct products as a growing number of individuals are being released from hospital to home instead of skilled facilities.

DMEPOS manufacturers and distributors cannot absorb the significant cost increases for raw goods, production, shipping, import freights, and supply chain economics, so they are passing it through to suppliers. The most recent data published by Health Industry Distributors Association (HIDA) from March 2021 reveals that it takes:

- **2.5 times longer to ship products and 4 times the cost to ship containers.**
- **3 times longer to dock and unload when arriving at ports, resulting in 1-2 week unloading delays in US ports.**
- **62% increase in e-commerce over the past year, exacerbating driver shortages.**
- **37% increase in freight volume by truck over the last year.**

These costs are being shouldered by DMEPOS suppliers who continue receiving price increase notifications from their vendors as well as increased delivery and operational costs while facing fixed reimbursement rates. Delivery costs alone have increased by 33% on average during the pandemic including roundtrip expenses with vehicle cost, labor, PPE, and time to set up equipment, educate beneficiaries and/or family caregivers, and pick up equipment. The increased cost of hiring and retaining workforce has also made an impact on supplier financials. Many of these added cost pressures will continue long after the PHE concludes and threaten the viability of DMEPOS suppliers to continue to meet the needs of their communities.

From seniors to those with disabilities or chronic conditions, people across the country rely on DMEPOS to go about their daily lives and manage their medical needs in a cost-effective home environment. However, this equipment cannot save lives if it is not available to those who need it most, especially in rural communities where we know barriers to access health care already exist.

In 2020, Congress took swift and decisive action to protect non-bid areas affected by the pandemic by providing a 50/50 blended rate for rural areas and a 75/25 blended rate for non-bid, non-rural areas in the CARES Act of 2020. After the passage of the CARES Act, CMS issued a DMEPOS final rule which provides the 50/50 blended rate for rural areas after the PHE. This rule did not extend the relief to non-bid, non-rural areas. As costs continue to climb, Congress must act to extend the 75/25 blended rate for non-bid, non-rural areas for two years after the end of the PHE.

3a. CMS wants to further advance health equity across our programs by identifying and promoting policies, programs, and practices that may help eliminate health disparities. We want to better understand individual and community-level burdens, health-related social needs (such as food insecutity and inadequate or unstable housing), and recommended strategies to address health inequities, including opportunities to address social determinants of health and burdens impairing access to comprehensive quality care.

Examples may include, but are not limited to:

- Identifying CMS policies that can be used to advance health equity:
    - Recommendations for CMS focus areas to address health disparities and advance health equity, particularly policy and program requirements that may impose challenges to the individuals CMS serves and those who assist with delivering healthcare services;
    - Recommendations on how CMS can better promote and support accommodations, including those from providers and health plans, for people with disabilities and/or language needs or preferences;
    - Input on how CMS might encourage mitigating potential bias in technologies or clinical tools that rely on algorithms, and how to determine that the necessary steps have been taken to mitigate bias. For example, input on how we might mitigate potential bias with clinical tools that have included race and ethnicity, sex/gender, or other relevant factors. Further, input on potential policies to prevent and/or mitigate potential bias in technology, treatments or clinical tools that rely on clinical algorithms.
    - Input on how CMS coverage and payment policies impact providers, suppliers, and patients, especially in the treatment of chronic conditions and the delivery of substance use disorder and mental healthcare, including individuals who are dually eligible for Medicare and Medicaid; and
    - Feedback on enrollment and eligibility processes, including experiences with enrollment and opportunities to communicate with eligible but unenrolled populations.

AAH Response:

AAH will not respond.

3c. Recommendations for how CMS can promote efficiency and advance health equity through our policies and programs.

AAH Response:

AAH will not respond.

3b. Understanding the effects on underserved and underrepresented populations when community providers leave the community or are removed from participation with CMS programs.

AAH Response:

AAH will not respond

4a. CMS wants to understand the impact of waivers and flexibilities issued during the COVID-19 PHE, such as eligibilty and enrollment flexibilities, to identify what was helpful as well as any areas for improvement, including opportunities to further decrease burden and address any health disparities that may have been exacerbated by the PHE.

Examples may include, but are not limited to:

- Impact of COVID-19 PHE waivers and flexibilities and preparation for future health emergencies (e.g., unintended consequences, disparities) on providers, suppliers, patients, and other stakeholders.

AAH Response:

The DMEPOS industry strongly supports the Agency's decision to make significant accommodations and suspend certain Medicare requirements to facilitate the ability of suppliers to take care of an increased number of beneficiaries in their homes, avoiding hospitalizations and easing hospital overflow issues. We thank the Agency for timely implementation of the new fee schedules in non-rural, non-competitive bid areas, consistent with Congress' directive in the Coronavirus Aid, Relief, and Economic Security Act.

The industry supported CMS' waivers on audits during the PHE. Early in the pandemic, as the world was closing operations, most suppliers were focused on providing care and did not have the staff to respond to audits. We appreciate that CMS chose to close all active audits early in the pandemic and put a hold

on certain audits through the pandemic. The industry also supported CMS' decision to restart TPEs only for items that did not have an active waiver.

The industry also supported CMS' decision in the 1744-IFC to waive all face-to-face encounters, explicit or implied, for the duration of the PHE, to minimize in-person contact. CMS states: "to the extent that an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications, or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic." The waiver of the face-to-face encounters in the provision of DMEPOS was important during this pandemic, as there were many instances in which the DMEPOS supplier was required to have in-person encounters with the beneficiary in his/her home. There are also numerous requirements for the beneficiary to return to the prescribing physician for an in-person visit, often for the physician to certify continuing medical need, or the need for additional supplies to use with the prescribed DME.

The expansion of Telehealth services to facilitate access to care while minimizing in-person encounters had a significant positive impact on serving beneficiaries during the PHE. The DMEPOS industry has received positive feedback from patients and proved to be an effective alternative for some in-person visits. The waiver has greatly improved the access to care without compromising the quality of services. AAHomecare strongly recommends the expansion of Telehealth services to remain permanently after the PHE.

However, the industry did not support CMS' decision to not require accreditation for newly enrolling DMEPOS suppliers earlier in the PHE that was announced in a FAQ titled, "Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19." CMS also waived certain screening requirements for DMEPOS supplier applications and expedited the review process for new applications from suppliers. In the absence of a demonstrated access issue to DMEPOS suppliers, we did not support these relaxations because they may have the unintended effect of promoting potentially fraudulent and abusive behavior by new entrants. For future PHEs, we recommend CMS allow the accreditation organizations to use their judgement regarding the relaxation of their standards during this PHE.

DMEPOS suppliers expressed that understanding all the different requirements at different levels were challenging, especially because they were constantly evolving. Suppliers indicated they relied on industry organization (federal and state) resources to better understand the federal and local requirements.

In addition, there were some waivers that were not defined clearly that added confusion for suppliers. For example, early on in the pandemic, CMS published in a FAQ that all signatures were waived, but it was later clarified verbally by the DMEPOSMACs that only Proof of Delivery signatures

were waived. This type of direction should have been more clearly defined in writing. Why waive only one signature if the purpose is to avoid the in-person interaction?

4b. Recommendations for CMS policy and program focus areas to address health disparities, including requested waivers/flexibilities to make permanent; any unintended consequences of CMS actions during the PHE; and opportunities for CMS to reduce any health disparities that may have been exacerbated by the PHE.

AAH Response:

With the end of the PHE approaching, the DMEPOS industry is concerned that once the PHE ends, beneficiaries that were set-up during the PHE or received on-going services during the PHE may not meet the required Medicare clinical indications for coverage. CMS needs to ensure beneficiaries that were serviced under the PHE waivers, such as oxygen and CGM beneficiaries, will continue to have access to their items and therapy post-PHE. For example, oxygen and CGM beneficiaries who were set-up or received services during the PHE may never meet the standard Medicare requirements; however, their prescribers have determined their need for continued therapy. CMS needs to ensure these Medicare beneficiaries can continue their oxygen and CGM therapy by not requiring requalification under current Medicare requirements.

While the relaxation of certain requirements was a positive and necessary step, there remain unanswered issues and ambiguities that require resolution to provide DMEPOS suppliers with reasonable assurance that the suspended application of certain rules will be upheld in the event of post-payment or other audits. With respect to audits conducted after the PHE has ended, on claims submitted with dates of service during the PHE, AAHomecare recommends that CMS clarify that any audits be focused on ensuring that medical record documentation is consistent with the requirements in place during the PHE. For dates of service post-PHE, CMS needs to ensure that audit contractors understand that the beneficiary's records may not comply with all of the coverage requirements due to the PHE. As an example, if the beneficiary should have had a repeat sleep study or physician appointment during the PHE and it did not occur, the medical record will never be entirely complete and yet the beneficiary may be continuing with therapy post PHE. In addition, AAHomecare urges that post-PHE audits place a priority on claims where there is a reasonable suspicion of fraud.

AAHomecare recommends CMS to update, finalize, and adopt the draft clinical data elements (CDEs) available on CMS' website. We strongly recommend that CMS make them mandatory for hospital systems and physicians revised versions of the CDEs. Such revised CDEs would facilitate the collection of medical need documentation, and could be incorporated into e-prescribing systems, which are

becoming increasingly prevalent in the DME industry. Adoption of CDEs and making them the only documentation needed to meet medical necessity would greatly improve the provider burden and secure suppliers are collecting all the needed documentation.

For future PHEs, the industry recommends CMS to require Medicare Advantage plans to accept all the same waivers and accommodations as Medicare FFS. The communication related to DMEPOS by Medicare Advantage plans were minimal. The discrepancies between the two Medicare programs created inequity for suppliers and beneficiaries.