August 26, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445—G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies (CMS-1611-P)

Dear Administrator Slavitt:

I am writing on behalf of the Alliance for Home Health Quality and Innovation (the "Alliance") in response to the Centers for Medicare and Medicaid Services' (CMS') request for Public Comment on the proposed rule, **Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies (CMS-1611-P) ("Proposed Rule").** [1] Thank you for the opportunity to provide comments on the Proposed Rule.

About the Alliance for Home Health Quality and Innovation

The Alliance is a non-profit 501(c)(3) organization with the mission to lead and support research and education on the value of home health care to patients and the U.S. health care system. Working with researchers, key experts and thought leaders, and providers across the spectrum of care, we strive to foster solutions that will improve health care in America. The Alliance is a membership-based organization comprised of not-for-profit and proprietary home health care providers and other organizations dedicated to improving patient care and the nation's healthcare system. For more information about our organization, please visit: http://ahhqi.org/.

We appreciate the opportunity to provide comments on the Proposed Rule, and offer recommendations and considerations to CMS on the following topics: (1) home health care's value proposition; (2) the impact of Medicare home health payment rate changes and patient

[1] Medicare and Medicaid Programs; CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements, Vol. 81, No. 128 Fed. Reg. 43,714 – 788 (July 5, 2016) (herein after "Proposed Rule"), https://www.gpo.gov/fdsys/pkg/FR-2016-07-05/pdf/2016-15448.pdf

access to care; (3) proposed changes to outlier payments; (4) proposed billing changes to disposable negative pressure wound therapy; (5) the proposed Home Health Groupings Model; (5) home health value-based purchasing updates; and (6) IMPACT Act measure updates.

I. Home Healthcare's Value Proposition

Home health care continues to serve important roles in the U.S. healthcare system, providing high-quality, cost-effective, and patient-preferred care.

Particularly in the context of formal post-acute care, analysis of Medicare claims data has shown that home health care is often the most cost effective option for patients and the health care system at large. For example, Medicare expenditures for a patient receiving home heath care in the 60 days following a hospital stay are nearly $8,000 less than the overall average Medicare post-acute care episode cost when a patient goes to home health as the first post-acute care setting ($20,345 versus $28,294).[2] Additionally, within the context of major joint replacement procedures, which are the subject of Medicare's Comprehensive Care for Joint Replacement (CJR) model, the cost savings associated with patients who receive home health care immediately following hospital discharge highlight the need for home health care in a changing delivery landscape. In the 67 participating Metropolitan Statistical Areas (MSAs) in the CJR model, the historical average Medicare episode payments for MS-DRG 470 (major joint replacement without major complication or comorbidity) was $24,900 compared with $19,900 for when home health was the first post-acute setting of care.[3] This data analysis demonstrates the critical value of home health in new and emerging payment models.

Cost savings is not the only driver in establishing home health's value within the health care system writ large. Patients who use home health also see outcome improvements as reflected in a number of key metrics. According to data from Home Health Compare, 89.8% of wounds improved or healed after an operation for patients following a home health episode. This is coupled with additional data that shows that 70.2% of patients had less pain when moving around, 70.6% get better at bathing, and 69.2% had improved breathing after receiving home health care.[4] On average, home health agencies nationwide have been improving over time as well, with improvements compared to the 2014 and 2015 averages for these measures. Further, the post-acute care payment reform demonstration project commissioned by CMS showed patients who received home health care were more likely to improve their ability to

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[2] Allen Dobson, et al., Improving Health Care Quality and Efficiency ("Final Report"), Clinically Appropriate and Cost-Effective Placement (CACEP) Project, Dobson | DaVanzo (Nov. 9, 2012), http://ahhqi.org/images/pdf/cacep-report.pdf

[3] Dobson | DaVanzo & Associates Distribution of Patient Episodes, Readmission Rates, and Average Total Episode Payment According to CJR Payment Model, by MSA for CJR Participating Hospitals (May 12, 2016) http://ahhqi.org/images/uploads/_Summary_Tables_MSA_Level_061616_v2.pdf

[4] Data from the 2015 Home Health Compare national data average for critical quality measures of home health agencies, Jul. 13, 2016 https://data.medicare.gov/Home-Health-Compare/Home-Health-Care-National-Data/97z8-de96

self-manage their care as compared to patients who went to other post-acute care settings. This was true even after adjusting for severity of condition.[5]

Finally, in general patients prefer to receive services at home as opposed to a facility when clinically appropriate. [6] Continued access to home health care for older Americans is therefore essential to maintaining the long-term viability of caring for such a large and growing population. Continued payment cuts threaten to reduce access to home health care, eventually leading to high costs and lower quality of care long term.

Home health is already a critical partner for care delivery, as demonstrated in its value within the CJR model. CJR, however, is just one way home health can play a critical role in future delivery models. Within a number of new and alternative payment and delivery models, home health agencies are critical partners to support the care of older Americans. Home health agencies partner with primary care professionals to support Medicare beneficiaries during periods of exacerbation when skilled nursing and therapy is important to prevent unnecessary hospitalization. In addition, home health agencies also partner with home-based long-term care providers; older Americans who wish to age in place may experience periods when home health agencies are needed to provide skilled nursing and therapy in the home, and prevent unnecessary institutional care. The home health agency of the future seamlessly connects to patients and families, primary care, and long-term services and supports through technology enabled, patient- and person-centered care which addresses medical and chronic illness in order to prevent unnecessary hospitalizations and/or facility care.[7]

Thus, the Alliance urges CMS to consider the role and value of home health care in the overall health care system as it makes changes to the home health prospective payment system. While the Alliance supports a number of the proposals in the proposed rule, the Alliance remains concerned about changes and reductions to payment which could negatively affect the ability of home health providers to fulfill their ability to serve patients and the health care system optimally.

II. The Alliance continues to be concerned with the changes to Medicare home health payment rates and the newly introduced pre-claim review, and the impact they may have on access to quality and efficient care for beneficiaries.

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[5] CMS, Report to Congress: Post Acute Care Payment Reform Demonstration (PAC-PRD) (Jan. 2012), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Flood_PACPRD_RTC_CMS_Report_Jan_2012.pdf

[6] According to the AARP, persons 50 and older with disabilities, particularly those age 50 to 64, strongly prefer independent living in their own homes to other alternatives. Preferences for services at home rather than in nursing homes are widespread among persons with disabilities. Even in the event they needed 24-hour care, 73 percent of persons with disabilities prefer services at home. Among the general population of persons 50 and older, 58 percent prefer services at home.
http://assets.aarp.org/rgcenter/il/beyond_50_il.pdf

[7] Alliance for Home Health Quality and Innovation Appendix D: Vigenttes (June 2016)
http://ahhqi.org/images/uploads/APP_B_Vignettes.pdf

The Alliance offers comments from the perspective of how patient access to quality care may be impacted by the proposed payment changes articulated in the proposed rule, and encourages CMS to consider the comments submitted by the National Association for Home Care and Hospice, the Visiting Nurse Associations of America, and the Partnership for Quality Home Healthcare with regard to specific rate-setting.

a. Home health payment rate cuts threaten access to high quality care for patients who are poorer, sicker, and older than the general Medicare population, and threaten the efficiency of the health care system.

Every year, the Alliance updates a Home Health Chartbook, a compilation of descriptive statistics from government data sources that includes the Medicare Current Beneficiary Survey, the Bureau of Labor Statistics, the U.S. Department of Commerce, Medicare Cost Reports, Home Health Compare, Medicare fee-for-service claims, and other data from the Centers for Medicare and Medicaid Services. The Chartbook is intended to shed light on the demographics of home health users, the clinical profile of home health users, and multiple dimensions of home health care in the United States. The Alliance's partner in generating the data in the Chartbook is Avalere Health, LLC.

Data from the 2015 update to the Home Health Chartbook shows that between 2010 and 2013, the number of home health users with two or more Activities of Daily Living (ADL) limitations has increased significantly. As the chart below illustrates, in 2010, just 2.5% of home health users lived with two or more ADL limitations, compared to 31.9% just four years later in 2013. The percentage of home health users with incomes under 200% of the Federal Poverty Level (FPL) have also risen significantly over this period of time, going from 62.6% to 67.2% from 2010 to 2013.[8]

Demographic Trend of Home Health Users

Table 1.23: Selected characteristics of Medicare Home Health Users, 2010 – 2013

	2010	2011	2012	2013
Have 3 or more chronic conditions	86.0%	83.2%	85.9%	85.1%
Have 2 or more ADL limitations*	22.5%	28.7%	34.2%	31.9%
Have incomes under 200% of the Federal Poverty Level (FPL)**	62.6%	64.5%	67.9%	67.2%
Have incomes under 100% of the Federal Poverty Level (FPL)**	30.2%	34.8%	32.6%	31.2%
Are dual eligibles***	N/A	29.9%	29.9%	31.7%
Have SMI****	N/A	26.3%	27.0%	27.2%

Source: Avalere analysis of the Medicare Current Beneficiary Survey, Access to Care files 2010 – 2013
*ADL = Activities of daily living, such as eating, dressing, and bathing. Limitations with at least 2 ADLs is considered a measure of moderate to severe disability and is often the eligibility threshold for a nursing home level of care.
**100 percent of FPL for a household of was $10,830 in 2010, $10,890 in 2011, $11,170 in 2012 and $11,490 in 2013 . 200 percent of FPL was double each amount.
***Dual eligibles are defined as individuals with any state buy-in at any point during the year. Beneficiaries were classified as requiring assistance with an ADL (bathing, walking, transferring, dressing, toileting, and eating) if they reported needing at least stand-by assistance with that ADL.
****Severe mental illness (SMI) is defined as having depression or other mental disorder, including bipolar disorder, schizophrenia, and other psychoses.

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[8] Excerpt from Home Health Chartbook, 2015: Prepared for the Alliance for Home Health Quality and Innovation, Chart 1.23 (http://ahhqi.org/images/uploads/EXCERPT_2015_AHHQI_Chartbook_Section_1.pdf).

These are not small changes, and in fact, they may help to explain the increase in severity of home health cases served by HHAs over the last few years. Coupled with an increase in the number of home health users who are dual eligibles, as well as the percentage of home health users who have severe mental illness, the need for access to high-quality home health care is rising.[9]

The Alliance urges CMS to consider the following demographic and clinical data on home health patients as the data show how vulnerable the home health patient population is.[10]

Demographics of Home Health Users

Table 1.6: Selected Characteristics of Medicare Home Health Users and All Medicare Beneficiaries, 2013

	All Medicare Home Health Users	All Medicare Beneficiaries
Age 85+	24.0%	12.0%
Live alone	36.7%	28.8%
Have 3 or more chronic conditions	85.1%	62.5%
Have 2 or more ADL limitations*	31.9%	12.0%
Report fair or poor health	48.7%	27.2%
Are in somewhat or much worse health than last year	41.9%	22.2%
Have incomes at or under 200% of the Federal Poverty Level (FPL)**	67.2%	52.1%
Have incomes under 100% of the Federal Poverty Level (FPL)**	31.2%	21.3%

Source: Avalere analysis of the Medicare Current Beneficiary Survey, Access to Care file 2013
*ADL = Activities of daily living, such as eating, dressing, and bathing. Limitations with at least 2 ADLs is considered a measure of moderate to severe disability and is often the eligibility threshold for a nursing home level of care.
**In 2013, 100 percent of FPL for a household of 1 was $11,490, a household of 2 was $15,510, a household of 3 was $19,530, and household of 4 was $23,550. 200 percent of FPL was double each amount.

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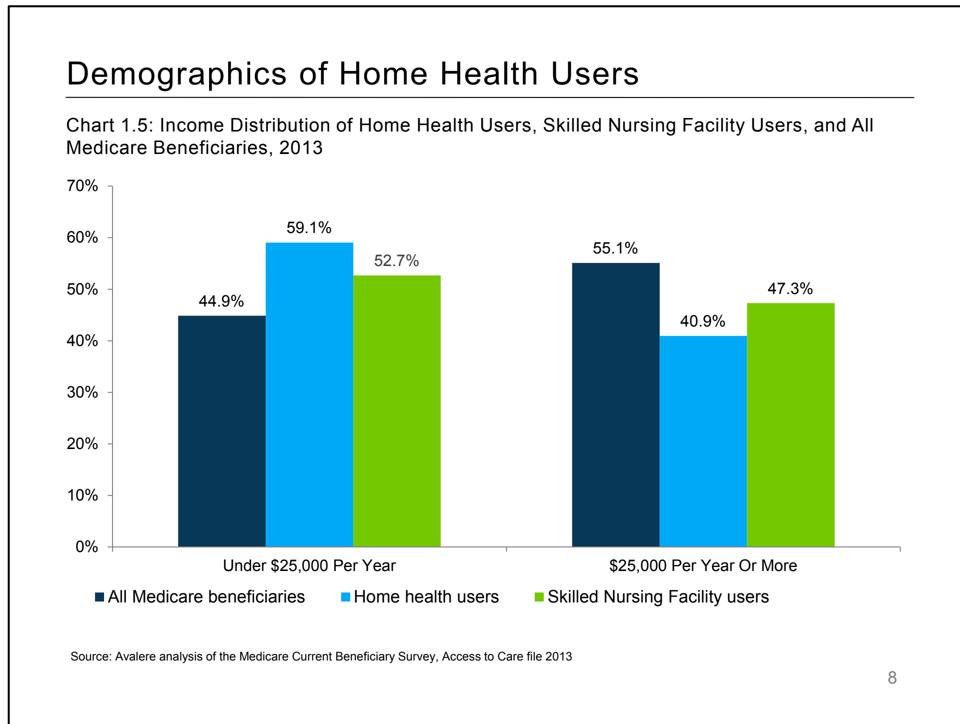
[9] *Id.*

[10] All of the Charts inserted in the Alliance's comments below can be found at http://ahhqi.org/images/uploads/EXCERPT_2015_AHHQI_Chartbook_Section_1.pdf



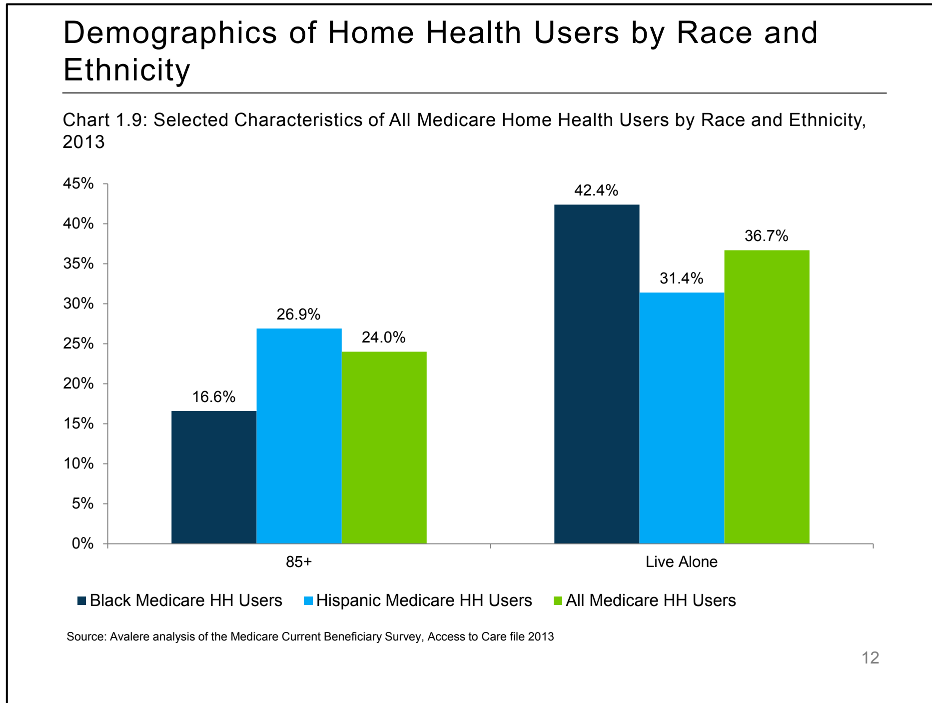
Medicare home health patients tend to be older, sicker, and poorer than the general Medicare population. Among Medicare home health beneficiaries, almost one in every four is over 85 years of age, and more than one in every three lives alone. By comparison, only 12.0% of all Medicare beneficiaries are aged 85 or older. Additionally, 67.2% of home health users have income below 200% of FPL; by comparison, only 52.1% of general Medicare beneficiaries have income under 200% of the FPL. Furthermore, as reflected in the proceeding chart, home health users tend to suffer from more chronic conditions, are more likely to report fair, poor, or worsening health, and have more limitations on their activities of daily living ("ADLs") than their peers.[11]Chart 1.5 demonstrates that home health agencies tend to serve a greater percentage of those making less than $25,000 per year than SNFs and all Medicare beneficiaries.

Additionally, home health agencies tend to serve a higher proportion of racial minority patients as compared with skilled nursing facilities.[12] Black and Hispanic home health users tend to be even poorer than the general home health population, and poorer still compared to the general Medicare population. Higher percentages of Black and Hispanic patients also tend to have 2 or

[11] *Id.* at 9.
[12] *Id.* at 7 (Chart 1.4 shows that racial minorities comprise 21% of home health users, compared to 15.3% of skilled nursing facility users).

more ADL limitations and report fair or poor health. They are also older and more likely to live at home[13], making care even more difficult.

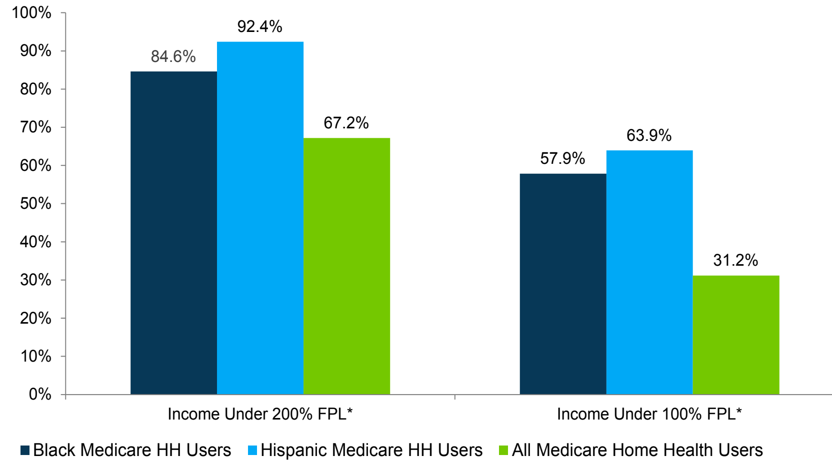
The Alliance is greatly concerned that continued payment reductions that have an impact on access and quality of care would have a disproportionately negative impact on racial and ethnic minority populations.



[13] *Id.* at 12.

Demographics of Home Health Users by Race and Ethnicity

Chart 1.11: Income by Federal Poverty Level (FPL) of Home Health Users by Race and Ethnicity, 2013



Source: Avalere analysis of the Medicare Current Beneficiary Survey, Access to Care file 2013
*In 2013, FPL for a household of 1 was $11,490, a household of 2 was $15,510, a household of 3 was $19,530, and household of 4 was $23,550. 200 percent of FPL is double those amounts.

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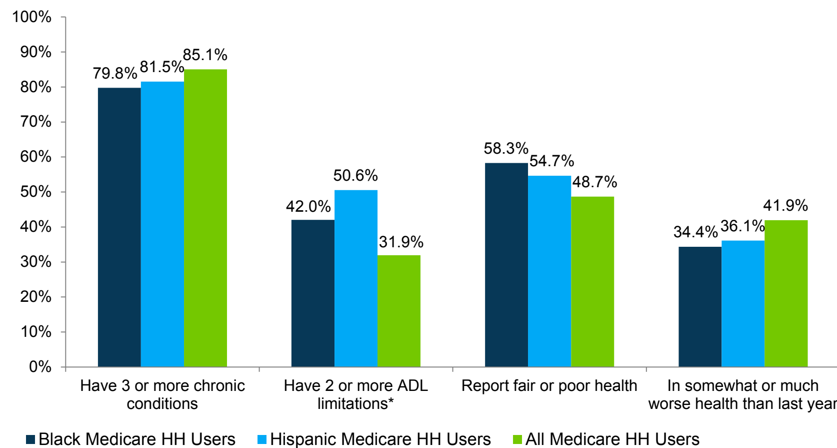
Demographics of Home Health Users by Race and Ethnicity

Chart 1.10: Health Status of Home Health Users by Race and Ethnicity, 2013



Source: Avalere analysis of the Medicare Current Beneficiary Survey, Access to Care file 2013
*ADL = Activities of daily living, such as eating, dressing, and bathing. Limitations with at least 2 ADLs is considered a measure of moderate to severe disability and is often the eligibility threshold for a nursing home level of care.

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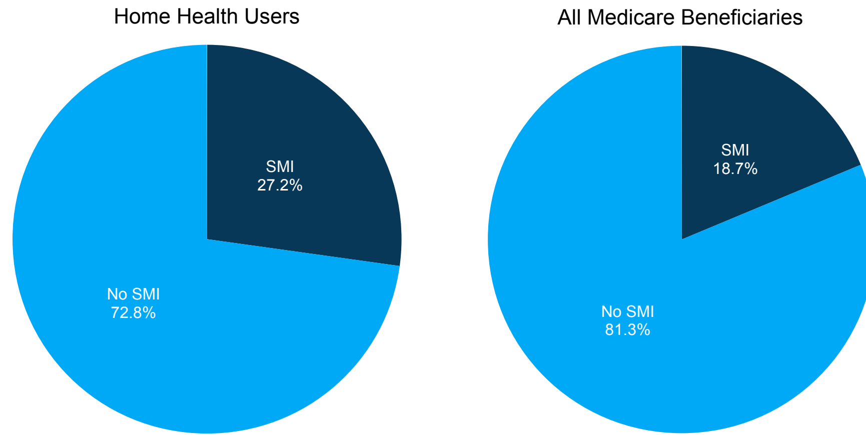
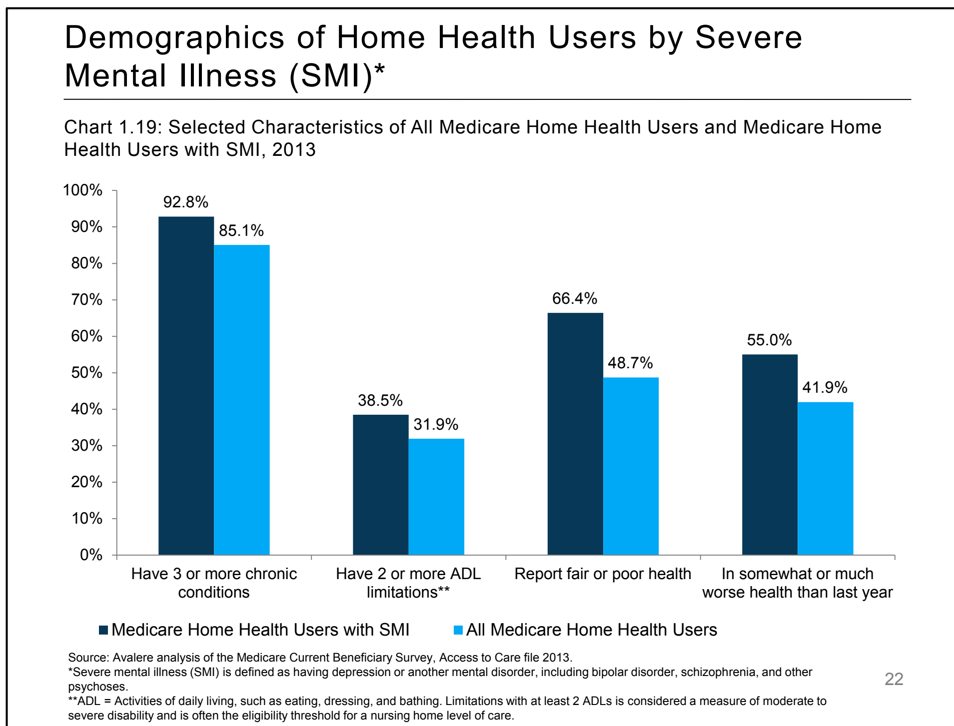


Payment cuts also disproportionately threaten access to care for patients with severe mental illness. More than a quarter of all home health beneficiaries are managing severe mental illnesses, as compared to 18.7% of all Medicare beneficiaries.

Home health beneficiaries who have severe mental illness also tend to be more vulnerable than the Medicare population at large, as described in Chart 1.19.



The rebasing and case mix adjustments that will result in home health payment rate reductions jeopardize access to quality care for patients who are in greatest need of protection. Moreover, the rate reductions threaten the ability of home health providers to make necessary investments to provide better care for patients and the entire health care system.

Recommendation: Due to the risk for reduced access to critical care for the most vulnerable population, the Alliance urges CMS to consider the potential impact of payment cuts on a generally, older, sicker, poorer, and more vulnerable population, and mitigate these risks where possible.

b. **The pre-claim review demonstration,[14]announced by CMS in June 2016, imposes an administratively burdensome utilization management process that threatens patient access to care for a highly vulnerable population.**

As discussed above, home health beneficiaries represent a critically frail and vulnerable patient population as compared to the general Medicare population. Given the great needs of home health beneficiaries, focus should be on improving, rather than hindering, access to home health care for a growing population of older Americans. The pre-claim review demonstration, which CMS announced in June of this year, compounds the already complex process of delivering home health care and severely threatens patient access to care in the identified states (Illinois, Florida, Texas, Michigan, and Massachusetts). The pre-claim review demonstration is a major concern for a growing population of Medicare beneficiaries who rely on home health care to provide high-quality care in their preferred home setting.

The Alliance is concerned that this demonstration will be administratively infeasible.. Unlike durable medical equipment, for which a prior authorization process has been tested, home health agencies provide care that is subject to a physician-established plan of care developed for each unique individual. Each plan of care is different and tailored to individual needs; therefore, reviews will not be simple and cannot be reduced to an algorithm.

Moreover, pre-claim review presents a regulatory hurdle that further challenges the ability of agencies to provide person-centered care. Rather than expending previous home health agency resources on efforts to improve the quality of patient care, the pre-claim review process will necessitate investments in staff time spent on collecting documentation and communicating with Medicare contractors on the pre-claim review process. The pre-claim review process will heighten administrative complexity and force home health agencies to increase overhead to focus on paperwork. In considering whether to accept a patient, agencies will no longer only consider whether a beneficiary meets the requirements of the home health benefit; rather agencies will be forced to focus on whether any given patient's records will pass muster with the MAC's staff that will be performing pre-claim review. This difference likely will have an impact on patient access to home health care.

Furthermore, CMS does not have express legal authority in statute to pursue a pre-claim review demonstration for home health care. There is no specific statutory provision to authorize conduct of a demonstration project on pre-claim review for home health services..CMS cites 42 U.S.C. § 1395b-1(a)(1)(J) as legal authority to carry out the pre-claim review demonstration as a means of testing methods for "investigation or prosecution of fraud." This demonstration, however, tests a method of screening and utilization management, not "investigation or prosecution of fraud." Even if CMS did have legal authority to carry out the pre-claim review demonstration, the mandatory nature of this demonstration that affects five entire states should require CMS under the Administrative Procedure Act to use notice and comment rulemaking.

While the Alliance is fully committed to addressing fraud, waste, and abuse, pre-claim review is an ineffective means of targeting and eliminating fraud. Instead, the Alliance would welcome

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[14] Medicare Program; Pre-Claim Review Demonstration for Home Health Services, Vol. 81, No. 112 Fed. Reg. 37,598 – 600 (June 10, 2016) (herein after "Pre-Claim Review"), https://www.gpo.gov/fdsys/pkg/FR-2016-06-10/pdf/2016-13755.pdf

working with CMS on ways to target fraud and abuse, and would support development of a CMS and HHS Office of the Inspector General's (OIG) public-private working group aimed at identifying methods of eliminating fraud and abuse in home health care.

c. **Given that home health patients tend to be more racially diverse and less wealthy than the general Medicare population, the Alliance urges CMS to further consider risk-adjusting for socioeconomics and race.**

As demonstrated above, home health patients are poorer and more racially diverse than the general Medicare population and the skilled nursing facility population. Particularly as IMPACT Act measures are seeking to enable cross-setting comparisons, it will be critical to risk adjust appropriately for these factors. The social determinants of health should be a focus of risk adjustment in measure development and maintenance. As value-based purchasing in Medicare becomes the norm, taking socioeconomics and race into account will support access to high quality care.

Recommendation: The Alliance recommends that CMS risk-adjust home health performance measures for race and socioeconomic status given the diversity of the home health population.

III. Proposed Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device

1. Recognizing Home Health Agency Services

The Alliance is concerned that CMS's proposed payment policy for negative pressure wound therapy (NPWT) using a disposable device does not adequately recognize the home health agency's services in furnishing NPWT.

a. Interpretation of Section 504 of the Consolidated Appropriations Act of 2016

CMS proposes that in instances where the sole purpose of a home health agency visit (by a registered nurse, physical therapist or occupational therapist) is to provide NPWT using a disposable device, that Medicare will not pay for the visit under the home health prospective payment system. Rather, CMS proposes to have the furnishing of NPWT using a disposable device paid using the hospital outpatient prospective payment system (OPPS) amount, which CMS states, "includes payment for both the device and furnishing the service."[15] CMS states that "the HHA must bill these visits separately under type of bill 34x . . . along with the appropriate HCPCS code . . . Visits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x)."[16]

This billing approach is inconsistent with Section 504 of the Consolidated Appropriations Act of 2016 (Pub. L. 114-113) because the statute explicitly sets payment only for the disposable

[15] 81 Fed. Reg. 128 at 43743.
[16] *Id.*

NPWT device, not the service related to NPWT. Section 504 amends 42 U.S.C. 1395m by adding a section on "Payment for Applicable Disposable Devices", specifically mandating that the Secretary will make payment to a home health agency for "an applicable disposable device" as defined by the statute to be a disposable NPWT device that is a substitute for the durable medical equipment item for NPWT.[17] The statute also states that the "separate payment amount established under this paragraph *for an applicable disposable device* for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device."[18] Section 504 states and then reiterates that the statutorily mandated payment is being set for the device for disposable NPWT and that the payment rate is set at the OPPS rate captured in Level I HCPCS codes.

It is important to note that the statute does <u>not</u> mandate a payment amount for the furnishing of services associated with the NPWT disposable device, nor does the statute provide for payment of such services in combination with the disposable NPWT device as described in the Level I HCPCS codes (97607 and 97608). Rather, the statute specifies that separate payment for the disposable NPWT device is set at the APC rate that is associated with those codes. The reference to the Level I HCPCS code is for the purpose of identifying the APC rate at which the disposable NPWT device payment will be set.

Not only is the statute clear that this separate payment is for the disposable negative pressure wound therapy device only, the statute also specifies that the device payment is "separate from the payments otherwise made under section 1895,"[19] referring to payments under Home Health PPS. Thus, payments for the disposable NPWT <u>device</u> are separate from payments for <u>services</u> delivered by the home health agency relating to that device. The home health agency's service payments would be made under HH PPS. Furthermore, the home health agency's services relating to wound care more broadly for the beneficiary would also be separately paid. Thus, in either case, separate payment for the home health agency's services would be paid separately under HH PPS.

This interpretation of the statute is consistent with a Congressional intent to put a home health agency's incentives to have its patients use the disposable NPWT device on par with the incentives associated with the DME NPWT device. Currently, home health agencies are able to bill for a visit relating to the DME NPWT device. In order for disposable NPWT devices to be treated similarly, home health agencies should be able to bill for a visit relating to disposable NPWT devices.

b. Implications of Interpretation of Section 504

The implications of this interpretation are significant to enable consistent implementation of Section 504 and administration of HH PPS.

One issue that Alliance members have discussed is that NPWT using a disposable device often requires a maintenance visit, but CMS's proposed payment policy suggests that a maintenance

[17] 42 U.S.C. 1395m(s)(1)-(2).
[18] 42 U.S. C. 1395(s)(3) (emphasis added).
[19] 42 U.S.C. 1395m(s)(1).

visit would not be billable as a HH PPS visit. After a NPWT disposable device is provided to the patient, often a maintenance visit is needed to collect and remove exudate. CMS states that "[v]isits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x)."[20] If a home health nurse were to make a needed maintenance visit relating only to the disposable NPWT device, CMS's proposed policy of not permitting home health visits relating to the disposable NPWT device to be reported on a HH PPS claim would prohibit any recognition of such a visit using type of bill 32x. If CMS is paying for the HCPCS code, which includes both the NPWT disposable device and the related services, then the home health agency would not be able to use bill 34x for the maintenance visit because this code would already have been billed on an initial visit. To bill a maintenance visit using 34x would effectively pay the home health agency twice for the same disposable NPWT device.

By contrast, if CMS were to recognize that the statute simply mandates payment at the APC rate for only the disposable NPWT device, then on an initial visit (where only NPWT is furnished using a disposable device), the home health agency would be paid at the APC rate for the device, and would have a HH PPS visit that covers the related NPWT services furnished. The agency would bill 34x for the NPWT disposable device, and 32x for the home health agency's services relating to furnishing of NPWT on the visit. For the maintenance visit, the home health agency would bill 32x again for the services relating to furnishing NPWT using a disposable device (and would not bill 34x because the agency already billed for the NPWT disposable device at the initial visit).

This approach is similar to the one used for osteoporosis drugs. Home health agencies bill 34x to pay for the osteoporosis drugs, and bill 32x to be paid for the home health visit where the drug is delivered.

By allowing visits solely related to furnishing NPWT using a disposable device to be HH PPS visits billable using 32x, CMS will put the services related to furnishing NPWT on equal footing regardless of device, and avoid creating an incentive to use the DME version of the device instead of the disposable one. Currently, home health agencies that serve patients using NPWT using a DME device are able to bill for those visits using type of bill 32x as they are HH PPS visits. By allowing the service of furnishing NPWT using a disposable device to be a visit under the HH PPS, billable using 32x, CMS would appropriately allow for these visits to be counted as any other HH PPS visit. In doing so, CMS will avoid potential unintended consequences caused by different incentives relating to NPWT using a disposable device versus a DME device. In other words, if disposable NPWT-related home health visits cannot be billed under HH PPS, there may be an incentive to use the more costly, DME-version of NPWT.

Consistent with the foregoing, the Alliance urges CMS to modify its payment policies associated with NPWT using a disposable device and implement Section 504 of the Consolidated Appropriations Act of 2016 to clarify that bill 34x is to be used for payment to a home health agency only for the device, and bill 32x is to be used for payment for home health visits relating to furnishing of NPWT using such disposable devices.

2. Definition of "Applicable Disposable Device"

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[20] 81 Fed. Reg. at 43743.

In addition, the Alliance urges CMS to clarify the scope of devices included in the statutory definition of an "applicable disposable device." The statutory definition of an applicable disposable device is:

> "'(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a *non-manual* vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; (B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.'"[21]

The term "non-manual" is not defined in statute and not clarified in the proposed rule. The Alliance recommends that CMS clarify that non-manual vacuum pumps may operate by either electrical or mechanical means.

Further, the Alliance recommends that CMS hold to the interpretation of Section 504 as described in the Alliance's comments above, but use the HCPCS coding (97607 and 97608) as guidance for CMS's determination of the types of devices that would be appropriate to be considered an "applicable disposable device."

IV. The Alliance supports better alignment of outlier payments with cost of care, but has concerns about impeding access to care for certain patient groups.

a. Aligning outlier payments with the cost of care is a crucial step in the right direction.

The Alliance supports CMS's proposal to shift to 15-minute intervals, or units, of care over the current per visit methodology. By making this change, CMS will more accurately identify home health patients that are sicker or require more time and expense to serve. The current approach to identifying outliers by measuring the number of visits does not reflect how much time is spent at each visit. Shifting to 15 minute increments will enable better identification of outliers. Additionally, the Alliance remains supportive of the 10 percent outlier cap on agencies in an effort to improve program integrity and curb abuse.

b. Despite support for reviewing the current outlier payment methodology, the Alliance is concerned about the impact of the proposed caps on certain patient groups.

In the proposed rule, CMS is proposing to cap the amount of time in estimating cost of an episode for outlier payments to eight hours, or 32 units, per day and 28 hours per week. The Alliance believes this cap may create a disincentive to serve certain patient groups who require more care. Placing such a limit on the amount of care provided to patients hinders the ability to treat complex and higher severity patients who may be more sick and frail than the average patient. Such patients are already more vulnerable as a group and the proposed caps will

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[21] 42 U.S.C. 1395m(s)(2) (emphasis added).

impose limits that may hinder the ability to deliver needed care in the home. Applying these caps may even have the unintended consequence of disincentivizing agencies to take on sicker patients who are likely to be outlier patients.

As noted in section II of the Alliance's comments, home health patients overall are older, sicker, and frailer than the general Medicare population. Home health care also treats a wide variety of patients, and helps patients manage multiple comorbidities and chronic conditions. Nearly one quarter of all Medicare beneficiaries aged 65+ has at least five or more chronic conditions[22]. Home health patients are even sicker, with over 50 percent suffering from five or more chronic conditions.

Thus, the typical Medicare home health beneficiary is already much sicker than the typical Medicare beneficiary; outlier patients are the sickest of the sick, and home health agencies need to be paid appropriately to provide necessary care to these patients.

The Alliance is concerned that the proposed rule imposes caps that will hinder the delivery of clinically appropriate care for these extremely sick patients. These patients may need greater levels of care than the proposed cap allows. This may inadvertently drive some patients to skilled nursing facilities unnecessarily, increasing overall program cost by forcing patients who could receive home health care to instead receive more expensive facility-based care.

Furthermore, capping the hours of care at 28 hours per week with a review process which allows up to 35 hours per week of care, is 1) inconsistent with the language in the program manual specifying less than eight hours per day OR less than six days per week, and 2) creates an undue burden on providers by requiring additional paperwork in order to provide adequate care to outlier patients.

The Alliance believes that capping outlier payment hours at eight hours per day and 28 hours per week may hinder care provided to a very frail, and growing, population, when in fact the program manual itself allows for "extensions in exceptional circumstances when the need for additional care is finite and predictable."[23]

The Alliance supports the recommendations of the Visiting Nurse Associations of America on the per day and per week caps and urges modifications as follows to the proposed rule.

> ***Recommendation: The Alliance recommends that CMS eliminate the per day and per week caps for outlier patients, consistent with the language in Chapter 7 of the program manual.***

c. **The Alliance is concerned that the proposed weighting of outlier units will negatively effect certain patients.**

CMS proposes in its outlier payment methodology changes to give equal weight to each 15-minute unit. This approach does not accurately reflect the cost of delivering home health care.

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[22] Home Health Chartbook 2015 (page 9 Chart 1.6) http://ahhqi.org/images/uploads/AHHQI_2015_Chartbook_FINAL_October.pdf

[23] CMS Medicare Benefit Policy Manual, Chapter 7 (May 11, 2015) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf

Given that the reason for the changes to outlier payment methodology is to better estimate costs, the Alliance recommends that more weight should be given to the first 15 minute unit of a visit to provide a more accurate depiction of costs. The first 15 minute unit should be weighted more heavily than subsequent units because each visit requires additional cost associated with transportation to the home. Unlike facility-based settings, home health visits require transportation. To accurately capture home health costs, this factor must be taken into consideration.

This is especially important for insulin-dependent diabetics for whom shorter, but more frequent visits are required. The Alliance is concerned that without such a change, the proposed outlier policy may adversely affect insulin-dependent diabetic patients. From a policy-standpoint, CMS has explicitly identified such patients as ones that should be able to receive home health services. The program manual states:"The exception to the intermittent requirement is daily skilled nursing services for diabetics unable to administer their insulin (when there is no able and willing caregiver)." These patients may require assistance one to four times per day for frequent, short visits. The payment methodology for outliers will affect these patients because they do not require long visits, but do require frequent ones. The Alliance is concerned that the proposed payment methodology for outliers will not be adequate to cover the cost of providing their care. Inadequate payment may result in many of these beneficiaries without home health care, resulting in higher cost care at an institutional level, or no care at all, which may unfortunately result in poor patient outcomes and an unnecessary hospitalizations.

Further, given the potential impact on insulin-dependent diabetic patients and more, it is imperative that CMS provide greater detail and data analysis on how the outlier payment may alter payment. This is critical to understanding who may be left behind and a patient, and how these changes may impact access to care for certain patient groups. The outlier payment changes may drastically patient access to care, and therefore more data is needed on CMS's calculations in order to mitigate negative impact on patients.

The Alliance supports the recommendations of the National Association of Home Care and Hospice regarding outlier payment methodology and urges modifications as follows to the proposed rule.

> ***Recommendation: The Alliance recommends that CMS weigh the first 15-minute unit more heavily than subsequent units in order to more accurately reflect costs and ensure that insulin-dependent diabetics receive proper care.***

V. Home Health Groupings Model (HHGM)

The Alliance is interested in the HHGM model discussed in the proposed rule preamble, but is unable to provide detailed comments because of insufficient information at this juncture.

However, the Alliance has two high level concerns. First, the Alliance is concerned about separating patients based on referral sources, as CMS has not provided evidence within the proposed rule regarding differences in acuity for patients referred by facilities and hospitals versus community referrals. The Alliance strongly urges CMS to be transparent in providing evidence on patient severity differences. It is also important to note that new and alternative

payment models are evolving and having an impact on the patient populations served by home health agencies. Thus, even given the currently available evidence on patient severity differences, CMS's policy will need to be flexible to take evolving evidence into account.

Second, the Alliance urges CMS to be inclusive in its approach to the development of a new model in order to factor in provider perspectives. CMS has many possible means by which to receive public comments. In advance of receiving comments via notice and comment rulemaking, CMS can hold open door forums, town hall meetings and technical expert panels to welcome public input.

The Alliance welcomes the opportunity to work with CMS and provide input on the development of any proposed grouping model.

VI. Home Health Value Based Purchasing (HHVBP)

Overall, the Alliance supports the changes made to the HHVBP model within the proposed rule. The Alliance appreciates CMS's willingness to work with stakeholders on concerns regarding the identified quality metrics and cohorts. We look forward to continuing to work with CMS on HHVBP.

a. Smaller and Larger Cohorts

The Alliance supports the elimination of the cohorts for the purposes of calculating the benchmarks and achievement thresholds. The Alliance agrees with CMS's assessment that agencies in smaller-volume cohorts may be forced to meet standards inconsistent with larger-volume cohort HHAs, unfairly punishing agencies in the smaller-volume cohorts. The Alliance appreciate CMS's efforts to address these issues in the proposed rule.

b. Payment Adjustment Methodology

However, the Alliance is concerned about the size of the cohorts for the payment adjustment methodology. The payment adjustment methodology is critical to the success of the HHVBP model. The Alliance is concerned about the instability of using eight HHAs to define what constitutes a small cohort for the purposes of payment adjustment calculations. While the Alliance appreciates the analysis done by CMS to mitigate the effects of outliers on payment adjustments, the Alliance would appreciate further insight on whether an even larger cohort size, such as one with 12 HHAs—which was part of CMS's analysis—would further mitigate these variations without prohibiting the ability to evaluate HHVBP on competition between smaller-volume HHAs.

> *Recommendation: The Alliance recommends further information on the analysis done on cohort size for the LEF and payment adjustment methodology as concerns still persist as to the impact of outliers on cohorts with only eight HHAs.*

c. Quality Measures

The Alliance commends CMS and supports the language within the proposed rule to eliminate the following quality measures from the set of applicable measures: 1) Care Management: Types and Sources of Assistance; 2) Prior Functioning ADL/IADL; 3) Influenza Vaccine Data Collection Period; and 4) Reason Pneumococcal Vaccine Not Received. Neither the "Types and Sources of Assistance" and the "Prior Functioning ADL/IADL" measures had specifications and developing new performance measures for HHAs on such a quick timeframe would be risk-laden.[24] Moreover, the Alliance supports the effort to streamline the measure set. CMS should continue to pursue the goal of having a parsimonious measure set for the HHVBP model.

d. Appeals Process

Finally, the Alliance supports the proposed appeals process for HHVBP. The Alliance and its members appreciate the ability to utilize an appeals process.

VII. IMPACT Act Measures Under Consideration

Consistent with previous comments submitted to CMS and its contractors, the Alliance continues to have strong concerns regarding the proposed IMPACT Act Measures Under Consideration.

a. Medicare Spending per Beneficiary (MSPB)

As expressed in the Alliance's comments to Acumen in January 2016, the Alliance maintains concerns regarding episode length and the use of the national median as a benchmark for MSPB. [25]

With regard to length of episode, the Alliance is concerned about ending home health episodes at 60-days because there are patients who are discharged prior to the 60th day. Ending episodes at discharge will better align home health treatment periods with those of other post-acute care providers in terms of approach and methodology. Additionally, the Alliance would ask CMS to consider the issue of double-counting costs due to the current episode-length structure.

Further, the considerable geographic variation in health care renders the use of the national median problematic. If CMS does not want to establish a permanent model for regional benchmarks, one approach could be to consider a phased in approach that begins with use of regional medians and gradually moves to the use of national medians over the course of several years.

The Alliance recommends that CMS use regional benchmarks for MSPB-PAC measures to best account for geographic variation. Further, the Alliance urges CMS to reconsider length of

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[24] Alliance for Home Health Quality and Innovation Comments to CMS on Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies (Sept. 4, 2015) http://ahhqi.org/images/uploads/Alliance_Response_to_CMS_on_HHPPS_90415_WEB.pdf

[25] Alliance for Home Health Quality and Innovation Comments to Acumen on Draft Specifications for the Medicare Spending Per Beneficiary – PostAcute Care (MSPB-PAC) Resource Use Measures (Jan. 29, 2016) http://ahhqi.org/images/uploads/AHHQI_comments_on_MSPB_PAC_12916.pdf

episode determinants to allow for home health episodes which terminate before the 60th day to end at discharge, rather than at the end of the 60-day period.

b. Discharge to Community

Consistent with the Alliance's comments to RTI in November 2015, the Alliance continues to be concerned about certain aspects of the proposed discharge to community measure. Concerns include population variation and referral source for home health patients, outdated and burdensome coding, and issues arising from a lack of caregiver post-discharge.[26]

It is important to note that home health agencies are unique compared to other post-acute care providers because home health agencies provide care to community-referred beneficiaries in addition to hospital-referred beneficiaries. Home health agencies serve a wide-ranging population from a variety of referral sources. The target population for this measure for other post-acute providers such as SNF, IRF, and LTCH, is confined to referrals from an acute-care hospital, unlike home health. The Alliance is concerned that the measure as proposed purports to be a cross-cutting measure, but the varying target populations for the different post-acute settings will make comparisons across settings impossible. The Alliance recommends that the target population for home health match that of the other settings, so that only those admitted to home health within 30 days of discharge from an acute care hospital are included in the target population.

Additionally, the proposed measure uses specifications from ICD-9 codes despite the standardized code set moving to ICD-10 in October 2015. These codes should be cross-walked to avoid confusion and better predict the scope of the measure. HHAs also do not currently used discharge code 81 and adding it may present operational issues and an increased administrative burden.

Furthermore, the Alliance urges CMS to consider certain risk factors when implementing measures such as discharge to community. The Alliance recommends considered sociodemographic variables, along with dual eligibility status, for use in adjustment. Further, the Alliance asks CMS to consider risks associated with patients who do not have a willing and able caregiver upon discharge.

c. Potentially Preventable 30-Day Post-Discharge Readmission Measure

The Alliance remains concerned, consistent with previously submitted comments to RTI, about certain components of the potentially preventable 30-day post discharge readmission measure.[27]

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[26] Alliance for Home Health Quality and Innovation Comments to RTI on Draft Specifications for the Discharge to Community Quality Measure for Skilled Nursing Facilities, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, and Home Health Agencies (Nov. 23, 2015) http://ahhqi.org/images/uploads/Alliance_Comments_on_Discharge_to_Comm_112315.pdf

[27] Alliance for Home Health Quality and Innovation Comments to RTI on Potentially Preventable Readmission Measures for Post-Acute Care (Nov. 216, 2015) http://ahhqi.org/images/uploads/Alliance_Comments_on_Potentially_Preventable_Readmissions_111615.pdf

Post-acute care providers, especially home health agencies, are in a unique position with regard to patient readmission to acute care. Some home health patients are referred by other post-acute care providers to home health agencies. Patients who come from another post- acute care setting are at a higher risk for an additional readmission to the hospital. Furthermore, it is unclear which conditions would qualify as preventable readmissions. Further evidence and clarification is needed on what constitutes a preventable readmission. Patients who enter home health care directly, as well, should be risk adjusted separately from those who have come from multiple different PAC settings. Patients who have received care in multiple PAC settings are more frail and more likely to be at risk for readmission than patients who go directly to home health care.

Finally, as with the proposed discharge to community measure, the Alliance reiterates that given the update in coding set to ICD-10, it is critical to cross-walk the ICD-9 to ICD-10 codes.

d. Medication Reconciliation

Although the Alliance supports the use of a measure related to medication reconciliation, concerns persist with the specific language of the measure, as well as unnecessary burden that both HHAs and physicians may incur.[28]

First, greater clarity is needed on the language regarding "potential clinically significant" medication issues, as well as for what constitutes "significant drug interactions," "significant side effects," and "any potential adverse effects."

In addition, the follow-up time for the physician or physician designee is not clearly defined, and poses a risk of penalty for HHAs if they are unable to receive timely follow up from physicians, who may not be conscientious about following up with HHAs.

The Alliance recommends providing greater clarity on the language and definitions, as well on the timeline for physician follow up.

Finally, the Alliance continues to urge CMS to use further testing, validating, and self-reporting of each of these measures. Moreover, the Alliance strongly recommends that measures be NQF endorsed before including these measures in the home health quality reporting program. As stated above, numerous concerns exist with regard to each of the proposed measures and the Alliance remains very concerned about their implementation as proposed.

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[28] Alliance for Home Health Quality and Innovation Comments to NQF on CMS Measures Under Consideration (2015)
http://ahhqi.org/images/uploads/Alliance_Comments_on_CMS_Measures_Under_Consideration.pdf

The Alliance greatly appreciates the opportunity to comment. Should you have any questions about the Alliance's comments, please contact me at (202) 239-3671 or tlee@ahhqi.org.

Sincerely,

/s/
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Executive Director