

September 4, 2015

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 2016 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 2015 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Survey and Enforcement Requirements for Home Health Agencies ("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

¹ Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements, **Vol.** 80, No. 132 Fed. Reg. 39,840 – 914 (July 10, 2015) (herein after "Proposed Rule"), https://federalregister.gov/a/2015-16790

value proposition; (2) the impact of Medicare home health payment rate changes; (3) home health value-based purchasing; and (4) IMPACT Act implementation.

I. Home Healthcare's Value Proposition

Home health care presents a strong value proposition for individual patients and to the healthcare system at large: it offers quality care that is both cost-effective and patient preferred.

Particularly in the context of formal post-acute care, analysis of Medicare claims data has shown that home health is the least costly option for patients and the health care system at large. For example, Medicare expenditures for a patient receiving home heath care following a hospital stay are nearly \$8,000 less than the 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). For patients receiving care following a major joint replacement (MS-DRG 470), this difference is about \$5,000 per patient when comparing use of home health as a first setting of care to the overall average episode expenditures (\$18,068 vs. \$23,479).

Furthermore, more often than not, patient outcomes improved after receiving home health care. According to data from Home Health Compare, 89% of wounds improved or healed after an operation for patients following a home health episode. This is coupled with additional data that shows that 68% of patients had less pain when moving around, 68% get better at bathing, and 65% had improved breathing after receiving home health care.³ These numbers are improving as well, all up from their 2014 averages. Moreover, in the CMS commissioned post-acute care payment reform demonstration project that was completed by RTI, patients who received home health care were more likely to improve their ability to 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.⁴ Additionally, and perhaps most importantly, patients generally prefer to receive care at home, rather than in a facility.⁵

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 Data from the 2015 Home Health Compare national data average for critical quality measures of home health agencies, Jul. 15, 2015 https://data.medicare.gov/Home-Health-Compare/Home-Health-Care-National-Data/97z8-de96

⁴ 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

⁵ 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

Due to the critical need for home health care for a large, and growing, population, coupled with the benefits home health care provides to the U.S. healthcare system, serious concerns exist about challenges which threaten to cripple access and high quality care for patients moving forward. The payment cuts set forth in the Proposed Rule threaten patient access to quality home health care, thereby increasing the likelihood of an unnecessary institutional care episode. This improper utilization may lead to higher costs and poorer quality of care.

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. CMS has proposed very significant changes to home health payment in the proposed rule, and the Alliance is concerned that such changes 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 impact they may have on access to quality and efficient care for beneficiaries.

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. Reductions in home health payment rates threaten access to a patient population that is poorer, sicker, and older than the general Medicare population, and threaten the efficiency of the health care system.

The Alliance releases an annually updated 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.

Early 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 on the next page shows, in 2010, 22.5% 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 2013.⁶

⁶ 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).

	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 Beneficia "ADL = Activities of daily living, such as eating, dressing, a severe disability and is often the eligibility threshold for a n "100 percent of FPL for a household of was \$10,830 in 20 double each amount. "Dual eligibles are defined as individuals with any state by ""Dual eligibles are defined as individuals with any state by the state of the state of t	nd bathing. Limitations ursing home level of ca 10, \$10,890 in 2011, \$	with at least 2 ADLs is cons re. 11,170 in 2012 and \$11,490	in 2013 . 200 percent o	f FPL was

The significantly increasing functional limitations and socioeconomic vulnerability of home health users between 2010 and 2013 may explain the increasing severity of cases that HHAs have been seeing. Moreover, the percentage of home health users who are dual eligible has increased over time, as well as the percentage of home health users who have severe mental illness.⁷

These statistics on the demographic characteristics of home health users is from the Medicare Current Beneficiary Survey data for the years 2010 to 2013, the most current data available to date. It is noteworthy that the data analysis that CMS used for its analysis of case mix had been from 2011.

Recommendation: The Alliance urges CMS to re-consider its changes related to case mix adjustment in light of the recent data showing that between 2010 and 2013, increasing percentages of home health users are severely ill in terms of functional limitations and increasing percentages are poor in terms of income under 200% of FPL.

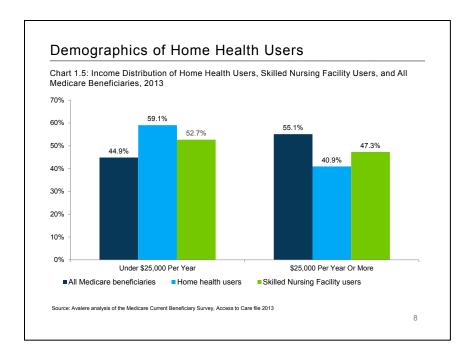
As acknowledged on pages 39,848 – 39,850 of the Proposed Rule, the current system of payments for home health may discourage home health agencies from serving those patients who are clinically complex and/or have multiple chronic conditions. Therefore it is imperative to consider the most vulnerable populations and the demographics of home health users when implementing payment cuts. The Alliance urges CMS to consider the following demographic

and clinical profiles of home health patients when making decisions that will affect a vulnerable patient population.⁸

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%		
Level (FPL)				

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.⁹

⁸ 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 ⁹ *Id.* at 9.



Additionally, as reflected in Chart 1.5, home health agencies tend to serve a greater percentage of those making less than \$25,000 per year than SNFs and all Medicare beneficiaries.

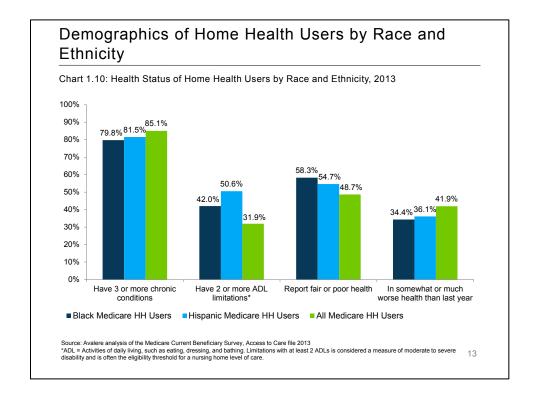
Furthermore, home health agencies tend to serve a higher proportion of racial minority patients as compared with skilled nursing facilities. Black and Hispanic home health users tend to be even poorer than the general home health population, and poorer still compared to the general Medicare population. Higher percentages of Black and Hispanic patients also tend to have 2 or more ADL limitations and report fair or poor health. They are also older and more likely to live at home making care even more difficult.

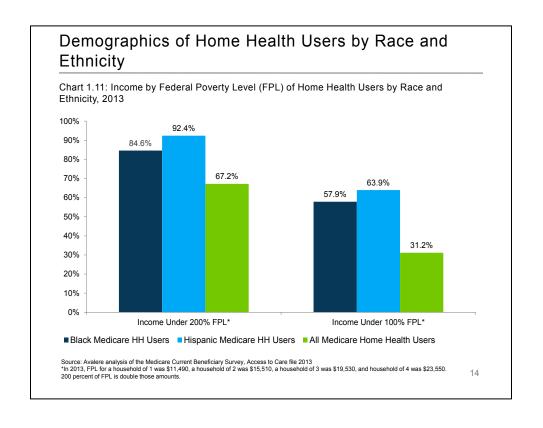
The Alliance is greatly concerned that payment reductions that have an impact on access and quality of care would have a disproportionately negative impact on racial and ethnic minority populations.

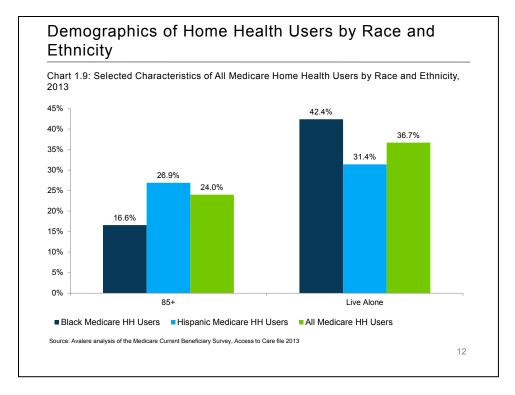
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 $^{^{10}}$ *Id.* at 7 (Chart 1.4 shows that racial minorities comprise 21% of home health users, compared to 15.3% of skilled nursing facility users).

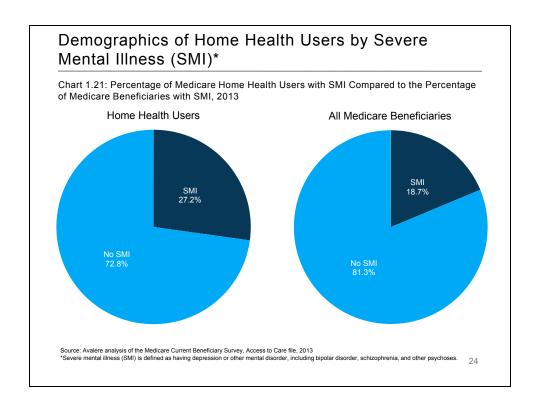
¹¹ *Id.* at 12.



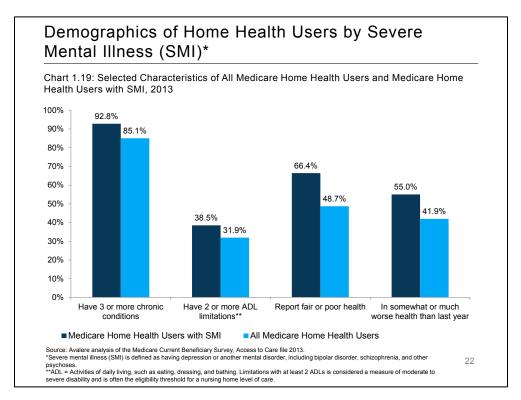




Additionally, payment cuts disproportionately threaten access to care for patients with severe mental illness. More than a quarter of all home health beneficiaries are managing severe mental illnesses, as compared to 18.7% of all Medicare beneficiaries.



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.



Reducing home health payments jeopardizes access to quality care for patients who are in greatest need of protection. Home health is often the lowest cost option for quality care, where appropriate, and is a preferred setting for aging in place.¹²

CY 2014 and CY 2015 both brought significant changes to home health payment rates, and further payment cuts in CY 2016 will threaten the ability to provide high-quality, lower cost care to the populations described above who need it most. In order to deliver quality care to patients, home health care providers must incur costs for appropriate skilled nursing and therapy services, workforce training, and infrastructure (including health information technology, which the Proposed Rule emphasizes as a critical means of improving health care). The Alliance remains concerned that even lower home health payment rates threaten the ability of home health providers to make such costly but 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.

¹² AARP, *Beyond 50.03: A Report to the Nation on Independent Living and Disability.* p. 177-178 (2003), http://assets.aarp.org/rgcenter/il/beyond_50_il.pdf

d. The Alliance agrees that health information exchange and health IT are vital to the continued improvement of care delivery and seeks further clarity on standards, stakeholder involvement, and incentives for creation and adoption of interoperable systems.

CMS discusses the importance of health information exchange and health IT in the proposed rule preamble in section II (D) on pages 39,844 and 39,845. Consistent with the comments the Alliance previously submitted in response to the Office of the National Coordinator's Shared Interoperability Roadmap¹³ and Federal Health IT Strategic Plan 2015-2010¹⁴, the Alliance urges CMS to consider a number of factors in increasing HIT adoption, including: standards, the role of stakeholders in the adoption process, and the financial burden of creation and adoption of HIT systems and networks. The final point is especially salient in light of the proposal for further payment cuts.

While currently home health providers are not eligible for Medicare and Medicaid EHR Incentive Programs, the Alliance urges ONC and CMS to consider additional policy levers and supports which go hand-in-hand with individual provider development of interoperable systems and networks. This may include incorporating health IT requirements to the Medicare Shared Saving Program ("ACO proposed rule"), and/or requiring meaningful use providers to be increasingly required to exchange health information with LTPAC providers such as home health providers. These possibilities may help to alleviate financial burden, while facilitating greater adoption.

Recommendation: The Alliance urges CMS to consider incentives for adoption and interoperability to improve quality of patient care and streamline processes for lower cost care.

III. Home Health Value-Based Purchasing

The Alliance supports the concept of home health value-based purchasing as a means to shift the traditional Medicare program towards payment that is tied to high quality, efficient care. The measurable goals set by the Secretary of HHS in January of this year to tie 85% of traditional Medicare payments to quality or value (e.g., through value-based purchasing or through readmissions reduction programs) by 2016 are laudable and the Alliance supports efforts to this end.

Notwithstanding, the Alliance has recommendations to refine the home health value-based purchasing model in the following areas: (a) measure considerations and the data sources used in home health value-based purchasing; (b) timeline for implementation; (c) the range of the incentive/penalty; and (d) process and evaluation of the pilot.

 $^{^{13}}$ Alliance for Home Health Quality and Innovation, *Alliance Comments to ONC on Shared Nationwide Interoperability Roadmap Draft* (2015),

http://ahhqi.org/images/uploads/Alliance Response to ONC on Interoperability Roadmap 040315 WEB.pdf

¹⁴ Alliance for Home Health Quality and Innovation, *Alliance Comments to ONC on Federal Health IT Strategic Plan 2015 – 2020* (2015),

http://ahhqi.org/images/uploads/Alliance Response to ONC on Federal Strategic Plan FINAL v02 0615 WEB.pdf

a. Measure selection and data sources used for value-based purchasing

At the core of achieving value-based care is the selection of measures that accurately reflect quality and efficiency in care delivery. The proposed model sets forth a very large number of measures, including both outcome and process measures. The Alliance has concerns regarding: (1) the sheer size of the measure set proposed and the absence of weighting or prioritization of measures, (2) the treatment of new measures and those not currently publicly reported, (3) the absence of NQF endorsement for many measures, (4) the need for a roadmap for performance measure updates, (5) the need for more public stakeholder input and engagement, and (6) clearer specifications related to performance data that is stratified by payer. The Alliance has recommendations regarding the treatment of new measures, updates to the measure set, and the data source used for the measures.

Size of Measure Set. The Alliance is concerned with the large number of measures proposed in home health value based purchasing. With twenty-nine total measures that are equally weighted, it will be difficult for home health agencies to focus quality improvement efforts meaningfully. This expansive approach invites a scatter shot approach to quality improvement that is infeasible. It would be preferable for the measure set to hone in on priority measures of interest to patients and to consider weighting them accordingly, or culling the set to eliminate measures deemed less, or even not, important. The Medicare Payment Advisory Commission has expressed similar concerns in its comment letter on the HHPPS proposed rule. ¹⁵

Recommendation: CMS should prioritize the measures that are included in the performance measure set and either limit the number or weight the measures consistent with priorities for patient care.

Treatment of New Measures. The proposed set of measures includes both existing measures and those that are new to home health care. For four proposed new measures (enumerated in Figure 4b at 80 Fed. Reg. 39880-39881), CMS proposes to have home health agencies earn points in the "Total Performance Score (TPS)" for only reporting data on these measures because these measures are new to home health agencies.

Recommendation: The Alliance supports this approach toward new measures and further recommends that for all new measures to home health agencies that are not currently publicly reported for at least one year, home health agencies should earn points in the TPS for reporting only for a period of at least two years.

In addition, it is important to note that there are two new measures not currently reported by home health agencies – neither publicly reported, nor shared with individual agencies – that have been included in the proposed starter set for measurement, and home health agencies would earn points based on performance to be included in the TPS (rather than reporting only). These two measures are "Care Management: Types and Sources of Assistance" (OASIS M2102) and "Prior Functioning ADL/IADL" (NQF #0430). Neither of these measures is

 $[\]frac{15}{http://medpac.gov/documents/comment-letters/medpac-comment-on-cms's-proposed-rule-on-the-home-health-prospective-payment-system.pdf?sfvrsn=0$

currently being used as home health agency performance measures. Although the OASIS M2102 is a current OASIS question/data element, it is not a measure of performance and it is unclear how this element would be incorporated as a performance measure in the proposed model. The Prior Functioning ADL/IADL measure is also new to home health agencies. It is unclear whether these are valid measures of performance for home health care. Furthermore, it is unclear why these measures have been selected and prioritized.

Recommendation: As with the measures that are not publicly reported, the Alliance recommends that these be treated as "proposed new measures" in the same fashion as the four proposed new measures that are in Figure 4b. In other words, the Care Management and Prior Functioning ADL/IADL measures should be ones for which home health agencies earn points for reporting, rather than performance, for at least two years. Moreover, the Alliance recommends that CMS provide an explanation as to the rationale for selecting and prioritizing these measures and ensure the measures are validated for home health performance measurement before agencies earn points for performance against them.

Use of a Formal Consensus Development Process. Of the measures proposed by CMS, many are not endorsed by a voluntary consensus-standards setting organization as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget Circular A-119. Although many of the measures are publicly reported, use of a formal consensus development process would serve the purpose of convening clinical and technical experts and stakeholders to thoroughly evaluate the measures against specific criteria. At the National Quality Forum, which is a voluntary consensus-standards setting organization, measures are evaluated for their suitability based on standardized criteria in the following order:

- 1. Importance to Measure and Report
- 2. Scientific Acceptability of Measure Properties
- 3. Feasibility
- 4. Usability and Use
- 5. Related and Competing Measures¹⁶

As a general rule, CMS should obtain endorsement of a measure from NQF or a similar body before including the measure in value-based purchasing. The Alliance recognizes that CMS has made home health value based purchasing a priority initiative. However, it is critical that a consensus development process be used for measures to be included in the testing of the HHVBP model. Issues may surface in the consensus development process that could be instructive for future refinements or changes to the measure. CMS should be open to the expression of diverse perspectives as these can ultimately strengthen the HHVBP program toward the ultimate goal of improving quality of care for home health beneficiaries.

Recommendation: Measures included in home health value-based purchasing should be endorsed through a formal consensus development process run by a national voluntary consensus-standards setting organization, such as the National Quality forum,

¹⁶ http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx

Updates to the Measure Set. Recognizing that CMS seeks to begin value-based purchasing next year consistent with the defined goals set by the Secretary, the Alliance urges CMS to iteratively update the home health measures that are included in value-based purchasing given the evolution that is expected in this area as a result of IMPACT Act implementation, movement towards alternative models of health care delivery, the use of star ratings, and the overall pursuit of the Triple Aim of improved patient experience, population health, and reduced per capita cost of care.

CMS has begun to provide a roadmap for development of performance measures in the context of IMPACT Act implementation and further measure development.

Recommendation: The Alliance recommends that CMS develop and publicize a roadmap for updating the measure set for home health value-based purchasing.

The parameters in such a roadmap for updates to the measures should include, but not be limited to, the following:

- Inclusion of measures of stabilization of condition where stabilization is a goal of treatment;
- Modifications to measures to build in adequate risk adjustment;
- Updating of measures to align with other CMS programs and priorities (e.g., Home Health star ratings, IMPACT Act implementation, alternative models of health care delivery such as ACOs and the CCJR model);
- Retiring measures as needed (for example, if measures have topped out).

The roadmap should also clearly articulate the patient care, quality and efficiency goals and principles for future changes to the measure set and the rationale for prioritizing certain changes over others.

The Alliance would welcome the opportunity to work with CMS to support identification of key areas for future updates and the development of the roadmap. Moreover, the Alliance appreciates that CMS has been convening technical expert panels on many topics and areas related to these issues, but is concerned that greater and broader stakeholder input is needed because of the wide array of stakeholders affected by the harmonization of measures and standardization of patient assessment data. Public opportunities for comment, such as town hall meetings, open door forums, and other means within CMS's power to hold open, public meetings would enable stakeholders to be informed, engaged and prepared for the changes ahead.

Recommendation: The Alliance recommends that CMS encourage more stakeholder involvement and engagement on a roadmap for home health value based purchasing by holding open public meetings (e.g., town halls, open door forums, and the like), sharing plans for the future, and inviting public comment at these public meetings.

Moreover, the ideal state would be to have some consistency and harmonization among measures used for the various CMS programs (e.g., home health value based purchasing, star

ratings, measurement used in alternative models of health care delivery) to the extent feasible and appropriate. It is critical, however, that the measures chosen for these programs be pursued based on a comprehensive and thoughtful roadmap consistent with the parameters identified above, and that is developed in a manner that is inclusive and open to stakeholder input.

Data sources. The proposed rule lists in Figures 4a and 4b the data sources for the measures enumerated, but is unclear as to which CMS programs will be included. For example, although the figures list certain measures that use specific OASIS data elements, the OASIS is collected for multiple CMS programs including traditional Medicare, Medicaid, Medicare Advantage, and Medicaid managed care programs. Similarly, HHCAHPS data is collected for multiple federal government programs. The scope of which program's data will be included in home health value-based purchasing is unstated in the proposed rule.

Recommendation: The Alliance recommends that for the traditional Medicare program's home health value-based purchasing model, the performance measure data should be drawn only from traditional Medicare.

Because the value-based purchasing model proposed only applies to traditional Medicare, the scope of the data used to calculate performance should likewise be limited to data from traditional Medicare.

Moreover, at present, agencies receive through the CASPER reports data on their performance against certain measures, but the data is aggregated to include all public payers. Because the patient mix varies by payer, it is important for agencies to receive performance data that is stratified by payer. This would be an important step towards understanding differences within the patient population.

Recommendation: The Alliance recommends that CMS provide home health agencies with data in the CASPER reports that is stratified by payer to enable understanding of differences in the patients served by the agency.

b. Timeline for implementation

In light of the numerous concerns with the proposed measures selected for the HHVBP model, the Alliance is concerned that implementation on January 1, 2016 would be premature.

Recommendation: The Alliance recommends phasing in implementation allowing at least one year (beginning HHVBP on January 1, 2017) to make modifications to the measure set, to develop a roadmap for updating performance measures with stakeholder input, to address the ability to adequately risk adjust and address critical measure gaps such as measuring stabilization, and to put measures for home health care through the NQF consensus development process. Moreover, the Alliance recommends that during 2016 CMS could begin sharing data with individual home health agencies on their performance against each measure, including the new measures, to validate and ensure the accuracy of the data.

It is important to recognize that data-intensive efforts, particularly if large numbers of measures are involved, will need to be refined. The Alliance recommends the above approach to allow for critical refinements and testing that will shore up the ultimate success of HHVBP. If, however, CMS pursues implementation by January 1, 2016, given the mandatory nature of the home health value based purchasing model, the Alliance recommends that CMS provide as much lead time as possible to enable home health providers in affected areas to prepare for implementation. Thus, if CMS implements the model on January 1, 2016, the Alliance recommends that CMS issue the final regulations and regulatory preamble for home health value-based purchasing as soon as possible and before November 1, 2015. Alliance members are supportive of home health value-based purchasing, but preparation for such significant changes would be supported by knowing the final states (or areas) selected, the finalized measures to be included, and the many details of the model as early as possible.

Recommendation: If implementation occurs on January 1, 2016, the Alliance recommends that CMS issue the final regulations and regulatory preamble for home health value based purchasing as soon as possible and before November 1 to enable provider preparation in the states or areas selected for the model's implementation.

c. Range of incentive/penalty

CMS proposes a five to eight percent incentive/penalty range for home health value-based purchasing. CMS proposes that for the first performance year (FY 2016), the adjustment would be up to 5%. For the next two performance years, the adjustment would be up to 8%. The Alliance is concerned that the range for the incentive/penalty is too large, particularly for a program that will present new and significant changes for home health providers. This is the first time a true pay-for-performance model will be applied to home health agencies on a large scale. The effects on patient care of such a large-scale program in home health care cannot be ascertained. Furthermore, the precedents for similar value-based programs in other provider contexts for traditional Medicare have much lower ranges for incentive/penalty. In the hospital context, the range of incentive/penalty for the hospital value-based purchasing program is only 2%. Similarly, for the skilled nursing facility value-based purchasing program, the range planned for that program is only 2%.

Moreover, the prospect of a 5 to 8% cut on top of the other proposed payment reductions for rebasing and case mix adjustment presents very significant concerns about patient access to care. Although CMS points out that most providers would fall within an incentive/penalty of approximately 1%, these payment reductions when considered in total are excessive and threaten both patient access and quality of care.

Recommendation: The Alliance recommends that the range for incentive/penalty for home health value based purchasing be limited to 2%, consistent with the value-based purchasing program in place for hospitals and the skilled nursing facility value based purchasing program to begin in FY 2019.

The Alliance further recommends holding the percentage of payment at risk steady at 2% during the entire course of the HHVBP model's testing. However, if CMS decides to increase the percentage of payment at risk, the Alliance recommends that any increase not exceed 1%

per year. Such an approach, allowing for gradual changes in the percentage of payments at risk, would also be consistent with the approach taken for hospitals.

d. Process and evaluation of the model

CMS proposes to test the home health value-based purchasing model under Section 1115A of the Social Security Act and has stated that the model would test whether being subject to significant payment adjustments would result in statistically significant changes in quality of care. The proposed rule proposes testing with performance years through CY 2020. The Alliance supports this testing, but it is unclear how CMS will evaluate the model, what specifically constitutes a successful outcome for CMS, how CMS will determine which components of the program are or are not successful, and what will be done with the lessons learned from the testing of the model. Overall, the Alliance recommends providing greater detail on how CMS will evaluate the overall effectiveness of the model, and an explanation of what CMS anticipates doing with this information. Transparently sharing plans for the evaluation and further anticipated next steps based on that information will enable home health providers to prepare for the future.

Recommendation: The Alliance recommends that CMS provide information on its plans for evaluation of the HHVBP model, and its anticipated potential next steps after evaluation of the model.

IV. The Alliance supports the intent of the IMPACT Act, however offers additional recommendations on IMPACT Act implementation.

As previously stated in Alliance comments on the Inpatient Rehabilitation Facility Prospective Payment System for FY 2016 proposed rule and the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) for FY 2016 proposed rule, the Alliance supports the intent of IMPACT Act: to develop a standardized patient assessment data set that is common across post-acute care settings in order to support quality measurement and reporting, future post-acute care payment reform, and coordination of care that supports achievement of the Triple Aim (improved patient experience, population health, and lower per capita cost of care).

a. The Alliance supports a clearer timeline, sequencing, and process for IMPACT Act implementation.

In order to best implement the IMPACT Act, and consistent with the Alliance's previous comments, the Alliance advocates CMS provide a clearer, step-by-step, timeline for the implementation of the IMPACT Act.

In the Proposed Rule, CMS outlines a general timeline for measure implementation, stating that:

Under the current HH QRP, the general timeline and sequencing of measure implementation occurs as follows: Specification of measures; proposal and finalization of measures through notice-and-comment rulemaking; HHA submission of data on the adopted measures; analysis and processing of the submitted data;

notification to HHAs regarding their quality reporting compliance with respect to a particular year; consideration of any reconsideration requests; and imposition of a payment reduction in a particular year for failure to satisfactorily submit data with respect to that year. Any payment reductions that are taken with respect to a year begin approximately 1 year after the end of the data submission period for that year and approximately 2 years after we first adopt the measure. To the extent that the IMPACT Act could be interpreted to shorten this timeline, so as to require us to reduce HH PPS payment for failure to satisfactorily submit data on a measure specified under section 1899B(c)(1) or (d)(1) of the IMPACT Act beginning with the same year as the specified application date for that measure, such a timeline would not be feasible. The current timeline discussed above reflects operational and other practical constraints, including the time needed to specify and adopt valid and reliable measures, collect the data, and determine whether a HHA has complied with our quality reporting requirements. It also takes into consideration our desire to give HHAs enough notice of new data reporting obligations so that they are prepared to timely start reporting data. Therefore, we intend to follow the same timing and sequence of events for measures specified under sections 1899B(c)(1) and (d)(1) of the Act that we currently follow for other measures specified under the HH QRP. We intend to specify each of these measures no later than the specified application dates set forth in section 1899B(a)(2)(E) of the Act and propose to adopt them consistent with the requirements in the Act and Administrative Procedure Act.

To the extent that we finalize a proposal to adopt a measure for the HH QRP that satisfies an IMPACT Act measure domain, we intend to require HHAs to report data on the measure for the year that begins 2 years after the specified application date for that measure. Likewise, we intend to require HHAs to begin reporting any other data specifically required under the IMPACT Act for the year that begins 2 years after we adopt requirements that would govern the submission of that data.¹⁷

As in the proposed rules for skilled nursing facilities and inpatient rehabilitation facilities, the Proposed Rule outlines a schedule for implementation of measures, but does not explain what changes will be made to standardize patient assessment data, and the timeline for implementation of those changes. There is discussion of submission and reporting of data, but no explanation of what assessment data changes will be made, when they will be made, and whether there will be an opportunity for comment on those changes. These are critical components of IMPACT Act implementation, but they appear to have been left out. For each post-acute care setting and provider affected by IMPACT Act implementation, it will be critical to understand what assessment data changes will be made, and when those changes will be made. The Alliance recommends that CMS include in the final rule the aspects of IMPACT Act implementation relating to standardization of patient assessment data in its timeline and sequencing.

However, it is important to note that the Alliance has significant concerns regarding the process CMS employs for selecting the measures that will apply to post-acute care providers. The IMPACT Act clearly envisions use of a "consensus-based entity" (such as the National

¹⁷ 80 Fed. Reg. at 39,894.

Quality Forum or "NQF") to endorse IMPACT Act measures, although it does state that the Secretary may specify a "feasible and practical" measure that is not endorsed "as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization." The Alliance has observed that some of the measures that CMS has selected for IMPACT Act implementation have been endorsed through NQF's consensus development process.

Other measures that CMS has identified for IMPACT Act implementation are going through the endorsement process at present, but have not yet achieved endorsement. Still other measures might apply only to one setting (for example, the long-term acute care hospital setting) and might be endorsed, or even presently going through the NQF process, but CMS is taking the measures and applying them across the board to all post-acute care settings. Although the goal of IMPACT is to develop standardized assessment data and quality measures that apply across all four formal post-acute care settings, having NQF endorsement of measures that apply to each and every post-acute care setting is critical. NQF endorsement of a measure developed for one setting, does not imply appropriate application for all post-acute care settings. Thus, for example, for the functional assessment and care plan development measure that applies to LTCHs, if NQF endorses that measure, such endorsement does not necessarily suggest that such a measure is appropriate for SNF, home health, and IRF settings.

NQF endorsement should be a pre-requisite for measures developed for application and use *in each and every setting*. Particularly for cross-setting measures, use of the NQF process is a key means to ensure consideration by all stakeholders. The NQF consensus development process is an important means of supporting the development of a uniform approach to measurement that makes sense in the face of different health care delivery modes in each post-acute care setting.

Recommendation: In the future, the Alliance recommends CMS use the NQF process consistent with the IMPACT Act and adopt cross-setting measures that are NQF-endorsed as they apply to each of the four post-acute care settings.

b. A more efficient, least burdensome approach to data collection is also needed.

Furthermore, as CMS goes forward with implementing standardized patient assessment data, the Alliance recommends that CMS take a least burdensome approach to data collection. The IMPACT Act states that:

In the case of patient assessment data being used with respect to a PAC assessment instrument that duplicates or overlaps with standardized patient assessment data within a category described in paragraph (1), the Secretary shall, as soon as practicable, revise or replace such existing data with the standardized data.

¹⁸ Social Security Act, Section 1899B((e)(2).

The Alliance is concerned about the burden potentially associated with completing multiple assessments to satisfy current requirements in MDS, IRF-PAI, and OASIS, and in addition to newer data element sets that are being put into place to comply with the IMPACT Act.

Recommendation: The Alliance urges CMS, where possible, to use an efficient approach to implementation that will avoid duplication of effort by providers and professionals. Further, the Alliance recommends that CMS include in the timeline and sequencing of implementation an explanation of when existing data elements will be changed or eliminated in exchange for new data elements implemented to comply with the IMPACT Act.

c. Greater clarity on, and a more streamlined approach to, the specifications for measures proposed for IMPACT Act implementation is critical.

In addition, as CMS proposes measures for IMPACT Act implementation, the Alliance urges CMS to streamline its approach to the regulations implementing the IMPACT Act and provide clarity involving the specifications for those measures.

The proposed and final rules issued annually by CMS to implement the payment systems for post-acute care are often vehicles for implementing various pieces of legislation. However, the IMPACT Act is a unique piece of legislation that is attempting to lay the groundwork for bringing together data collection and measurement for all four formal post-acute care settings. The IMPACT Act domains for measures of quality and resource use are meant to apply across settings, and it will be important to think of multiple aspects of the implementation with a mindset that is relative to those various settings. Being able to analyze the assessment data elements and measures collectively (and comparatively) with the other settings will be key to implementation.

As a result, the Alliance recommends in the future that cross-setting measures and assessment data changes that implement the IMPACT Act be addressed in stand-alone notice and comment rulemakings that apply to all four post-acute care settings. To the extent that payment and quality reporting programs are affected in each setting by the changes in measurement and assessment data, the individual payment system rulemaking processes can continue to be used to make those changes.

Furthermore, as stated above, the Alliance supports use of the NQF process for each measure as it applies to each post-acute care setting. Though the NQF process could be improved, overall it is an open and transparent process for reviewing measures. However, there may be circumstances where NQF endorsement is not achieved for a measure that CMS uses for IMPACT Act implementation or post-acute care in general. For example, though it is not preferable, there may be cases where CMS uses measures that are modified versions of measures that have been NQF-endorsed, uses measures that were reviewed by NQF but were not endorsed, or uses measures that have not gone through the NQF endorsement process at all. In the event that NQF endorsement has not been achieved for a measure, CMS's transparency involving measure specifications is critical. Such transparency is required in the

IMPACT Act, stating the importance of "informing the public of the measure's numerator, denominator, exclusions and any other aspects the Secretary determines necessary." ¹⁹

As evidenced by the fact that the measures proposed thus far for a given domain specified in the IMPACT Act have varied significantly in terms of the numerator, denominator, and exclusions for each post-acute care setting, the Alliance urges CMS to provide clear and transparent explanations of each measure's specifications, providing as much information as possible to the public about the measures proposed. The level of detail provided about a measure for endorsement through the NQF consensus development process would be helpful for all parties to understand the measures proposed through rule-making.

With respect to the specific future cross-setting and setting-specific measure constructs under consideration that were shared in Tables 22 and 23 of the proposed rule, the Alliance greatly appreciates that CMS has provided the information therein and the basic timeline for implementation that is consistent with the IMPACT Act's requirements. However, it is difficult to provide meaningful comment on the specific measures and measure constructs without further information. For example, for the "Medication Reconciliation" domain, the measure in the table is "Percent of patients for whom any needed medication review actions were completed." It is unclear from the table how one would determine whether a medication review action is needed for purposes of the measure.

Consistent with the recommendation above, the Alliance urges CMS to provide clear and transparent explanations of measure specifications and provide as much information as possible about the measures proposed, similar to the detail shared in the NQF consensus development process. To the extent that such detail has not yet been specified or resolved, the Alliance would welcome the opportunity to work with CMS in the development of these measures and their specifications.

d. Finally, the Alliance encourages CMS to engage further with postacute care stakeholders in order to understand and address changes to patient assessment data and measure specifications.

In recognition of the importance of the goals of the IMPACT Act, and the complexity and challenges that both CMS and the post-acute care provider community will face in implementing it, the Alliance recommends that CMS engage with post-acute care stakeholders on a frequent and regular fashion regarding both measure specifications and changes relating to standardized patient assessment data collection. Improved communications between and among the government and industry representatives can support and facilitate implementation of the IMPACT Act and the achievement of its goals. The feedback that key stakeholders can provide to CMS will enable smooth implementation of the IMPACT Act and achievement of the Triple Aim.

¹⁹ Section 1899B(e)(1)(A)(i) of the Social Security Act.

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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, /x/ Teresa L. Lee, JD, MPH Executive Director