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September 25, 2017

Submitted via: regulations.gov. .

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: CMS–1672-P: Medicare and Medicaid Programs: CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

Dear Administrator Verma:

The Centers for Medicare and Medicaid Services (CMS) and the U.S. Department of Health and Human Services have proposed a number of reforms in the Medicare home health benefit along with setting out CY 2018 payment rates in the Notice of Proposed Rulemaking (NPRM). 82 Fed. Reg. 35,270 (July 28, 2017). The changes include a completely new payment model that would take effect in CY 2019.

The National Association for Home Care & Hospice (NAHC) respectfully submits these comments regarding the proposals contained within the NPRM. NAHC is the largest trade association representing the interests of Medicare home health agencies (HHAs) nationwide

including nonprofit, proprietary, urban and rural based, hospital affiliated, public and private corporate entities, and government run providers of home health care since 1982. NAHC members provide the majority of Medicare home health services.

NAHC is also an original provider-member of the Leadership Council of Aging Organizations (LCAO) as it has put patients first in its health policy and advocacy positions since its inception. Each year, NAHC members serve millions of patients of all ages, infirmities, and disabilities, providing an opportunity for individuals to be care for in their own homes, the care setting preferred by virtually all people.

The NPRM includes a variety of proposed rule changes. Below, NAHC offers comment on most of those proposals.

A. CY 2019 PROPOSED PAYMENT MODEL REFORM

At the outset, NAHC states that it supports a modernization and improvement of the Home Health Prospective Payment System (HHPPS) case mix adjustment model. The Home Health Resource Groupings model (HHRG) has been handicapped since its inception with a crude method of payment adjustment that is dependent on the number of therapy visits provided to patients. NAHC originally cautioned against such method prior to the implementation of the HHRG model and has continually recommended that CMS replace the model.

NAHC is encouraged by CMS's efforts to devise a replacement model. The Home Health Groupings Model (HHGM) is the first publicly released proposal that offers a potential for replacing the HHRG model and its problematic "Utilization Domain." Due to the difficulties discussed below with the non-rate neutral proposal advanced in this NPRM, NAHC is handicapped in its ability to reasonably assess the merits of HHGM. Still, it is encouraging that a model has been developed that deserves consideration as a replacement for the flawed HHRG concept. NAHC is committed to working with CMS to advance the development and implementation of a valid and reliable case mix adjustment model that does not rely on therapy utilization volume as a primary determinant of the payment amount.

At the same time, NAHC cautions CMS to recognize the high value that therapy services have brought to both Medicare patients and Medicare itself. From the start of the HHPPS, the use of therapy services have maintained and/or brought patient improved functional capabilities and independence in life. In contrast to the pre-HHPPS era in home health, the increased use of home health therapy has reduced patients' length of stay, reduced hospitalizations and re-hospitalizations, improved quality of life allowing for self-care, reduced dependence on personal care supports, and controlled growth in Medicare spending in numerous benefit sectors. In the home health benefit alone, Medicare spending is far less today in 2017 that it was 20 years ago in

1997 while serving an equal number of Medicare beneficiaries annually at 3.5 million. No other Medicare benefit sector can make that claim.

As such, NAHC encourages CMS to continue to recognize the great value that therapy services has brought to Medicare beneficiaries and Medicare. Any payment model reform must balance incentives and disincentives to provide therapy so that timely and appropriate access to care is not burdened by the payment model.

NAHC concerns with the proposed payment model changes lie primarily with the payment rates that are based on unsupported assumptions of provider behavior changes. No matter how meritorious the case mix adjustment model is at distributing payment amounts, the whole system fails if the base payment rate is inadequate. Doing so will only mean reduced access to care for all types of patients. To assess any payment model reform, NAHC offers the following guiding principles. The proposed reforms do not meet those standards and **NAHC strongly recommends that the proposal be withdrawn.**

HOME HEALTH PAYMENT MODEL GUIDING PRINCIPLES

- 1. CMS should withdraw its proposal for instituting a new home health payment model starting in CY 2019 and instead work with home health services stakeholders to design, develop, and validate payment model reforms that would take effect on or after 2020 with at least 12 months lead time for effective implementation by HHAs.**

Rationale:

- a. There is no absolute need to finalize the new model at this time.
 - b. The proposed model is very complex and will certainly be disruptive whether it is a good or bad model. A later start date provides the opportunity to fully engage all stakeholders with comprehensive information on the reform options leading to the creation of a successful new payment model.
 - c. Resetting a target start date to 1/1/20 provides the needed time to perfect the new model, better understand its likely impact, and have HHAs prepare for it.
- 2. The home health care community supports implementing a new payment model with a patient classification system based on patient characteristics without reliance upon the volume of visits provided to patients to accurately determine the appropriate payment amount.**

Rationale:

- a. Utilization thresholds can create a risk of under or over-utilization. A model based on patient characteristics reflects the needs of the patient rather than utilization volume.
- b. Any new model that reasonably pays for care based on patient needs, without the use of utilization incentives or disincentives, is most likely to lead to appropriate clinical practice than a model based on visit volume. Such a model better recognizes the various needs of a diverse home health patient population and the value of all disciplines of care.

3. Payment model reform must be implemented on a fully rate neutral basis.

Rationale:

- a. Rate neutrality is a better health policy as Medicare home health agencies have been subject to a 4-year rate rebasing and other rate adjustments with rate reductions exceeding 16% since 2014. In 2018, HHAs face an additional rate reduction of approximately 1.4% in relation to cost inflation. On top of these reductions is a continuing 2% payment sequestration. The CMS Office of the Actuary estimates that 80% of HHAs are expected to face below cost reimbursement by 2040 with rate changes already on the books. The natural and foreseeable effect of a non-neutral reform is a barrier to care access and a threat to care quality. Previous non-rate neutral reforms in home health services caused significant harm, take many years to repair, and are difficult to correct. With the Interim Payment System (1998-2000), nearly 1.5 million Medicare beneficiaries lost access to care following the closure of over 4000 home health agencies.
- b. CMS has never before proposed non-rate neutral payment reform without specific Congressional authorization. Implementing any payment policy changes in a non-rate neutral manner is better done through the deliberative process of Congress. If CMS causes care access problems through rate cuts instituted by regulation, Congress must find budget offsets to cover the “cost” of fixing the mistake.
- c. The NPRM leaves uncertainty regarding the actual budget neutrality as the impact analysis relies on an undefined behavioral adjustment.
- d. CMS lacks the legal authority to impose non-budget neutral payment reform under the clear language of the Medicare statute, 42 USC 1395bbb.

THE PROPOSED PAYMENT RATES WOULD CRIPPLE HOME HEALTH AGENCIES AND SEVERELY RESTRICT ACCESS TO CARE

The proposed rule sets a base payment rate at one-half of the projected CY 2019 national, standardized 60-day episode payment amount plus the CY 2019 non-routine medical supply conversion factor amount with both adjusted by the applicable market basket index update divided by two. The CY 2018 equivalent of that formula would result in a base 30-day payment amount of \$1545.73 ($\$3038.43 + \$53.03/2$).

With this formula, CMS calculates that the impact on home health agencies if the new model is implemented in a non-budget neutral manner would be a 4.3% reduction in **spending** (\$950M) under the Medicare benefit. That calculation is the net outcome of undefined “assumptions on behavioral responses.” It appears that the undefined assumptions offset the spending reductions that otherwise result from the 30-day rate calculation by over two-thirds.

CMS reports that its calculations are based on data from 5,110,629 60-day episodes that convert to 8,642,107 30-day periods. Using the CMS calculated CY 2018 30-day payment amount (\$1545.73) and the 60-day payment amount (\$3091.46), the unadjusted impact is more than a 15% reduction in spending caused by a greater than 15% effective payment rate cut.

5,110,629 60-day episodes X \$3091.46 = \$15,799,300,000 (rounded)

8,642,107 30-day periods X \$1545.73 = \$13,358,400,000 (rounded)

\$13,358,400,000 divided by \$15,799,300,000 = 84.6% reduction in spending

While this calculation methodology may be considered simplistic, NAHC understands that more sophisticated have reached highly comparable outcomes. These calculations demonstrate that the actual spending impact through the 15.4% reduction in the base payment rate far exceeds the estimate offered by CMS in the NPRM. The difference can only be explained in the undefined “assumptions on behavioral responses.” **NAHC calculates a rate neutral base rate for a 30-day payment period at \$1,783.77.**

If these undefined assumptions prove to be baseless (see below discussion), the CMS proposed payment rates will result in much more significant reductions in Medicare spending

than the estimated \$950M in CY 2019. However, spending impact also is not a sensible determinant of impact on HHAs financial stability and the concomitant impact on care access. If payment rates are reduced below provider costs, an increased volume of services that would result in Medicare spending increases does not translate to financial stability for the HHAs. If HHAs experience a financial loss on every payment period, increased volume of payment periods, whether through extending the patient’s length of stay or increasing patient volume, only increases the HHA financial losses. Rate cuts trigger Medicare spending reductions, but service volume increases do not offset the financial impact of rate cuts.

To truly understand the impact of the NPRM on HHAs and Medicare enrollees, CMS must evaluate the impact of the NPRM on HHA financial stability not on the level of Medicare spending. Revenue neutral rate setting does not equate to rate neutral rate setting. In the case of home health care, non-rate neutral rate setting has consistently led to lost care access for Medicare patients. With the proposal for HHGM set out by CMS, HHAs will see drastic reductions in payment rates that jeopardize the existence of a majority of HHAs across the country, thereby directly threatening access to home health services.

NAHC analyzed the available FYE 2016 cost report database available through CMS. Consistent with the analytical framework used by the Medicare Payment Advisory Commission (MedPAC), NAHC trimmed cost reports that are considered unreliable and anomalous to calculate the 2016 Medicare margins of the HHAs based on 6,767 reports. NAHC then calculated the percentage of HHAs that would have negative Medicare margins if the proposed rates went into effect in CY 2019. Note that these findings relate only to Medicare Fee-for-Service (FFS) margins. Overall margins for HHAs in 2016 are an estimated 1.95%. With the proposed Medicare FFS rate changes, virtually all HHAs would experience an overall margin in 2019 that would be well below zero if the patients accepted into care and the level of services provided remained comparable to 2016 care access. Note that access problems will be created even if the rate reduction is equivalent to CMS’s calculated spending amount reduction of 4.3%

NATIONAL FINANCIAL IMPACT OF PROPOSED RATE CUTS

FY 2019 HHAs with Medicare FFS margins below 0% w/15% rate reduction	51.7%
FY 2019 HHAs with Medicare FFS margins below 0% w/4.3% rate reduction	33.0%
FY 2019 HHAs with Medicare FFS margins below 0% w/0% rate reduction	25.3%

STATE-SPECIFIC FINANCIAL IMPACT OF PROPOSED RATE CUTS

State	2016 Starting Value	Hypothetical 4.3% Rate Cut	Actual 15% Cut
	% of Agencies at or Below 0	% of Agencies at or Below 0	% of Agencies at or Below 0
Arizona	23.0%	28.7%	49.4%
California	25.5%	34.4%	56.6%
Colorado	26.9%	35.6%	46.2%
Connecticut	18.5%	20.0%	30.8%
District of Columbia	11.1%	11.1%	22.2%
Delaware	8.3%	8.3%	66.7%
Florida	20.8%	27.1%	44.0%
Georgia	9.8%	14.8%	41.0%
Guam	0.0%	0.0%	66.7%
Hawaii	37.5%	50.0%	62.5%
Iowa	37.6%	41.9%	61.3%
Idaho	42.9%	48.6%	60.0%
Illinois	29.3%	37.5%	61.7%
Indiana	35.8%	39.2%	51.4%
Kansas	43.7%	47.1%	65.5%
Kentucky	18.5%	23.1%	40.0%
Louisiana	21.1%	25.3%	44.2%
Massachusetts	18.3%	19.2%	37.5%
Maryland	11.9%	19.1%	38.1%
Maine	25.0%	35.0%	75.0%
Michigan	24.7%	31.9%	57.1%
Minnesota	33.3%	37.9%	52.9%
Missouri	35.8%	42.3%	58.5%
Mississippi	15.6%	28.1%	56.3%
Montana	18.8%	18.8%	37.5%
North Carolina	28.7%	33.3%	46.7%
North Dakota	71.4%	71.4%	100.0%
Nebraska	39.6%	41.7%	54.2%
New Hampshire	16.7%	25.0%	54.2%
New Jersey	21.1%	26.3%	50.0%
New Mexico	27.1%	32.2%	49.2%
Nevada	19.6%	33.0%	58.8%
New York	37.5%	47.5%	62.5%
Ohio	16.9%	21.9%	37.1%
Oklahoma	19.6%	25.1%	50.3%
Oregon	37.5%	47.5%	67.5%
Pennsylvania	13.2%	18.8%	36.2%
Puerto Rico	44.4%	48.2%	59.3%
Rhode Island	5.0%	5.0%	20.0%

South Carolina	30.2%	34.9%	55.6%
South Dakota	19.1%	33.3%	61.9%
Tennessee	15.9%	19.6%	42.1%
Texas	27.5%	33.9%	54.0%
Utah	24.3%	28.4%	50.0%
Virginia	23.8%	28.6%	48.8%
Virgin Islands	0.0%	0.0%	0.0%
Vermont	9.1%	27.3%	54.6%
Washington	27.7%	27.7%	42.6%
Wisconsin	42.4%	47.5%	66.1%
West Virginia	16.7%	25.0%	50.0%
Wyoming	6.7%	6.7%	33.3%

Note: These calculation estimates are based on 6,767 FYE 2016 cost reports. It can be expected that the estimated number of HHAs with Medicare margins below 0% would increase with full FYE 2016 data as historical data indicates that the as-yet unavailable HHA cost report data involves HHAs with low average margins.

CMS references the 2018 recommendations of the Medicare Payment Advisory Commission (MedPAC) in support of its proposal. However, while MedPAC recommended a 5% rate reduction, the CMS proposal is actually a rate reduction three times greater. NAHC disputes the sensibility of the MedPAC recommendation at 5%, but submits that a 15% rate reduction guarantees an access to care disaster.

The CMS proposal is also based on MedPAC-type logic that relies on gross averages and fails to recognize the wide variation in Medicare margins that occurs in a highly disparate delivery system where care is provided in all sorts of locations with different costs affected by travel time, resource availability, and care patterns outside on home health care. It is axiomatic that care delivered in rural Wyoming has cost differences compared to care provided in inner city Washington, D.C.

Those widely varying cost considerations and their impact are shown in the 2016 Medicare margin outcomes nationally and on a state-specific basis.

The national margin variation is dramatic, indicating that MedPAC averages are useless measures for purposes of evaluating impact of a rate cut at any level. It should be emphasized that a MedPAC-oriented “margin” is not the equivalent of a profit margin as many care and business costs are not included, e.g. telehealth; marketing.

2016 Medicare Margin Ranges

HHAs	Medicare Margin	Percentage of HHAs
690	< -25%	10.2%
104	-20% to -25%	1.5%
134	-15% to -20%	2.0%
213	-10% to -15%	3.1%
246	-5% to -10%	3.6%
334	0% to -5%	4.9%
519	0% to 5%	7.7%
617	5% to 10%	9.1%
650	10% to 15%	9.6%
720	15% to 20%	10.6%
643	20% to 25%	9.5%
1702	25% to 50%	25.2%
195	>50%	2.9%

It bears repeating that “Medicare margins” are not net profit margins. Medicare service costs are higher than those costs permitted to be reported on the cost report. In addition, overall net margins are much lower, 1.95% in 2016, when considering revenue and costs for other patients such as those covered under Medicaid and Medicare Advantage. Reducing Medicare fee-for-service rates has a compounding effect, negatively impacting on care access for such patients as well.

As Medicare FFS HHA margins drop, overall margins are significantly reduced. The decline in Medicare FFS and overall margins puts care access for all patient populations at risk, including traditional Medicare beneficiaries, Medicare Advantage enrollees, and Medicaid beneficiaries.

RECOMMENDATION:

CMS SHOULD NOT IMPLEMENT ANY NEW REIMBURSEMENT MODEL IN ANYTHING OTHER THAN A RATE-NEUTRAL TRANSITION

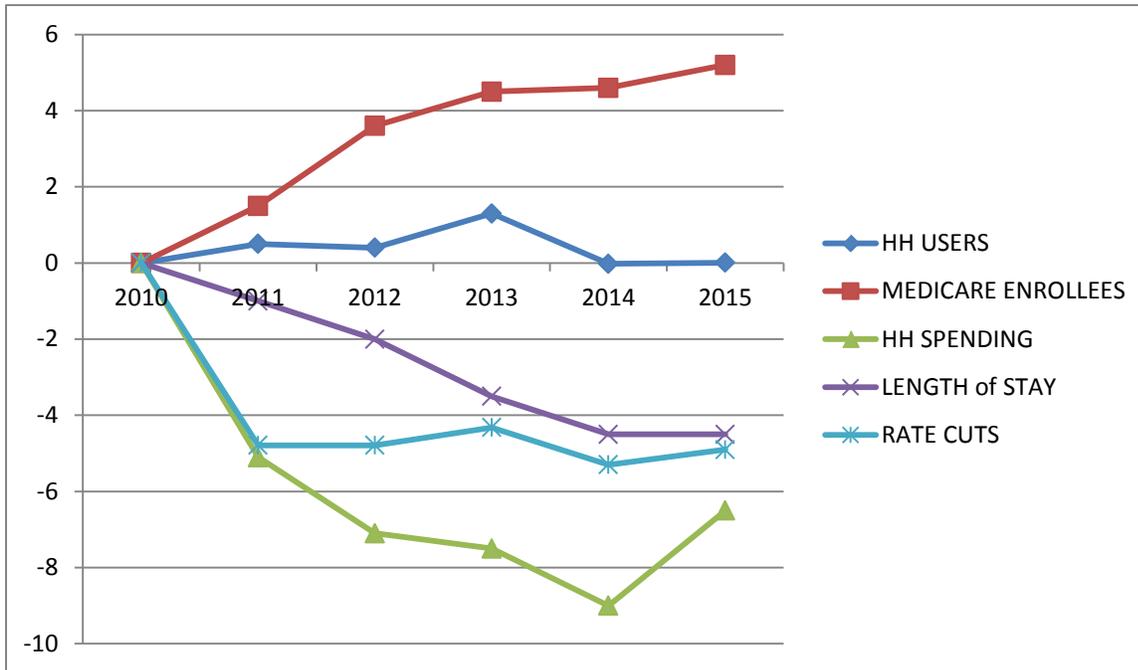
THE HOME HEALTH BEHAVIORAL ADJUSTMENT PROJECTED BY THE CMS OFFICE OF THE ACTUARY IS BASELESS

In developing the proposed Home Health Grouper Model (HHGM) for CY 2019, the Centers for Medicare and Medicaid Services (CMS) applied an undefined behavioral adjustment to calculate payment rates. As a result, CMS alleges that Medicare **spending** in 2019 would be cut by \$950 million or 4.3%. In the absence of that “behavioral adjustment,” NAHC estimates that Medicare **spending** on home health services would decline by approximately \$3 billion or 15.4%. CMS’s proposed CY 2019 rates with the behavioral adjustment are intended to be 4.3% less than **revenue neutral** for HHAs nationally, in the aggregate. However, “revenue neutral” has nothing in common with “rate neutral.” Payment rate neutral should have little impact on care access while revenue neutral can be a disaster for care access. With this proposal, that disaster is predictable.

It is notable that the CMS impact analyses focus on spending changes rather than rate or payment level changes. To achieve the \$950 million spending reduction estimate, CMS has reduced the payment levels (effective rates) by approximately 15.4%. There is a significant distinction between payment rates that are budget neutral and spending levels that are budget neutral. The CMS proposed payment levels (Rate X Case Mix Weight) are projected to be - 4.3% **revenue** neutral for HHAs in the aggregate when combined with the behavioral adjustment. With the significant rate reductions in the CMS proposal, cost report data indicates that a majority of HHAs will be paid less than their costs of care. No matter what HHAs do to increase service volume, the revenue increase will not affect the loss margin of these HHAs.

While the “behavioral adjustment” is undefined, it is believed that it is based on assumptions that home health agencies (HHAs) would increase the number of payment periods per patient and/or increase the number of patients served significantly. To account for the additional \$2 billion in spending change through the “behavioral adjustment,” it would be necessary for HHAs to increase the number of patients served by over 380,000 in the first year alone. Alternatively, HHAs would need to extend the length of stay for patients by nearly 1.3 million 30-day payment periods. However, the historical behavioral pattern of HHAs facing payment rate cuts shows no evidence that patient volume or per patient length of stay has occurred. In fact, rate reductions have historically led to reductions in the number of patients served and a decrease in the patient length of stay.

RECENT HISTORY 2010-2015



Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2015/2015_Utilization.html#Medicare%20Home%20Health%20Agency ; https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2015/2015_Enrollment.html#%20Fee-For-Service%20Medicare%20Enrollment

Rate cuts:

1. 7.86 points-- case mix weight adjustments
 - 3.79%(2011)
 - 3.79% (2012)
 - 1.32% (2013)
2. 3.0 points--- Market Basket Index
 - 1.0 (2011, 2012, 2013)
3. 5.1 points--- Rebasing
 - 2.7% (2014)
 - 2.4% (2015)
4. 2 points--- Sequestration (2011-2015)
5. 0.5 points--- Productivity adjustment (2015)

6. 0.6 points—Grouper change (2014)

Medicare FFS enrollees:	5.2% increase
Home Health Users:	0.8% increase
Episodes per User:	3.8% decrease
Home Health Spending:	6.6% decrease

These data evidence that the HHA response to rate cuts does not include an increase in patients or an increase in the length of stay to secure higher Medicare revenues. While Medicare FFS enrollees increased 5.2% between 2010 and 2015, home health users increased only 0.8%. In addition, the length of stay for patients decreased rather than increased with a 3.8% decline in the number of 60-day episodes per user. The rate reductions led to a decrease in Medicare spending on home health overall.

EARLIER HISTORY

The Congressional Budget Office (CBO) applied similar assumptions in scoring the Balanced Budget Act of 1997 (BBA 97), the last time significant payment reform was instituted for Medicare home health services. In that instance, CBO was not just wrong with its assumptions, it was disastrously wrong.

With the BBA 97, CBO projected that the home health payment changes would “limit the growth” of spending by \$16.2 Billion from 1998-2002. Further, CBO estimated that the changes would reduce Medicare spending by \$49.6 Billion from 1998-2007.

<https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/bba-97.pdf>. However, Medicare home health spending decreased by \$74.4 Billion from 1998 to 2002 and \$210.4 Billion from 1998-2007.

Spending	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	1998-2002	1998-2007
Projected	21.1	23.2	25.3	27.5	29.9	32.3	34.9	37.6	40.4	43.4	127	315.6
Actual	14.9	9.7	9.2	9.1	10	10	11.2	12.4	13.2	15.5	52.9	105.2
Difference											74.4	210.4

Sources: <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/bba-97.pdf> and https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/Downloads/2008_Section7.pdf#Table%207.1.

The underestimated negative impacts of the payment system changes are also shown in the number of Medicare beneficiaries who received home health services and the number of HHAs participating in Medicare. In 1997, 3.557 million Medicare beneficiaries used home health services. That number declined to a low of 2.402 million in 2001 after the BBA 97 was implemented. By 2007, it grew to 3.099 million. While CBO assumed that HHAs would immediately offset the payment rate reductions mandated in BBA 97 through increased utilization, <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/bba-97.pdf>, pp. 43-44, the annual and aggregate numbers declined significantly from 1997. The aggregate number of users in that period was 27.8 million. In contrast, the number would have been 35.57 million if the annual number of users remained steady from 1998-2007 instead of the growth that CBO assumed.

In Millions	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Total
Users	3.557	3.061	2.719	2.461	2.402	2.544	2.681	2.835	2.975	3.026	3.099	27.8
Users (no growth)	3.557	3.557	3.557	3.557	3.557	3.557	3.557	3.557	3.557	3.557	3.557	35.6
Diff.		0.494	0.838	1.096	1.115	1.013	0.876	0.719	0.582	0.531	0.458	7.8

Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareMedicaidStatSupp/Downloads/2008_Section7.pdf#Table%207.1.

The change in the number of HHAs precipitated by BBA 97 corresponds with the reduction in beneficiaries using home health services and Medicare spending for such care. Between 1997 and 2001, the number of HHAs declined by nearly 4000. As the program payments stabilized, the number of HHAs grew. However, by 2006 the number was still down 2093 in comparison to 1997.

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
HHAs	10,961 (est.)	9284	8000(est.)	7528	6800(est.)	6878	7223	7710	8219	8868

Sources: MedPAC assorted March Reports to Congress (note that MedPAC numbers are not consistent throughout)

CONCLUSIONS:

1. Medicare HHAs do not increase patient volume or extend patient length of stays in response to payment rate cuts
2. Payment rate cuts have restricted care access for Medicare beneficiaries
3. Assumptions of behavioral changes in response to rate cuts have been not only inaccurate, but the opposite of actual behavioral changes that occur
4. Any transition to a new payment model for HHAs must be rate or payment level neutral to ensure continued access to care
5. CMS's proposal to institute a new payment model is based on severely flawed "behavioral adjustments" and rate reductions that will trigger a care access disaster comparable to that which occurred following BBA 1997

RECOMMENDATIONS:

- 1. CMS should withdraw the "behavioral adjustment" as HHAs have not responded to rate reductions by increasing service volume**
- 2. CMS should ensure that any transition to a new payment model be done in a payment level or rate neutral manner in contrast to a revenue neutral approach that is based on unsupportable assumptions**

THE PROPOSAL TO IMPLEMENT A NEW PAYMENT MODEL IN A NON-RATE NEUTRAL MANNER VIOLATES MEDICARE LAW

NAHC submitted formal comments in the NPRM specific to the legality of the proposal to implement a non-rate neutral payment model reform on September 1, 2017. NAHC hereby incorporates those comments into this submission as Attachment A. However, as discussed above, NAHC also contends that transitioning to a new payment model that is a wholesale change as proposed should never be done in anything other than a rate-neutral manner as a matter of policy. Instituting an untried and untested system with the magnitude of changes contained in HHGM creates high risk of unintended consequences. Doing so in a non-rate neutral manner only amplifies those risks exponentially. Doing so with known history of serious adverse consequences to Medicare beneficiaries would be reckless.

THE NPRM VIOLATES THE ADMINISTRATIVE PROCEDURES ACT AND THE REGULATORY FLEXIBILITY ACT IN FAILING TO PROVIDE A LAWFUL AND APPROPRIATE IMPACT ANALYSIS SUFFICIENT FOR PUBLIC REVIEW AND COMMENT

While CMS recognizes the NPRM will have a significant impact on home health agencies, its impact analysis falls far short of what is required to comply with the Administrative Procedures Act, 5 USC Section 553, and the Regulatory Impact Act, 5 U.S.C. Sections 603 and 607. Not only does the impact analysis in the NPRM offer only an evaluation of the change in revenues that may be expected for home health agencies, it does so tainted by the undefined and baseless “assumptions on behavioral responses.”

The APA requires full disclosure of the basis for any regulatory proposal. Failing to disclose the nature and basis for “assumptions on behavioral responses” violates the APA as it is literally impossible for the public to comprehensively review the proposal and provide meaningful comments except by speculating as to the nature and basis for the behavioral adjustment. While NAHC believes that it has accurately deduced what the adjustment may be, that does not excuse CMS from its responsibility to clearly disclose this essential information under the APA.

Similarly, CMS must conduct a meaningful impact analysis. Here, CMS merely offers the net revenue impact calculation that is based on the undefined behavioral adjustment. As is addressed in detail earlier, the revenue impact is not the issue as much as it is the impact on financial stability stemming from the significant rate reduction that is based on the unstated

behavioral assumptions. The RFA requires such an impact analysis and the NPRM fails to provide it.

The legal shortcomings of the NPRM should be sufficient for CMS to withdraw the HHGM proposal. However, the actions of CMS in withholding complete information as to the nature and basis for the footnoted “assumptions on behavioral responses” highlight the APA and RFA violations. As NAHC has conveyed to both HHS and CMS during discussions occurring during the comment period, based on information and belief, NAHC is aware that CMS has intentionally withheld this essential information from the public. Such information is available and was also available at the time the NPRM was in development, yet CMS purposefully excluded that information from the published NPRM. Repeated requests for that information have been rejected.

COMMENTS REGARDING THE HHGM DESIGN AND OPERATION

In the event that CMS does not accept the recommendations set out above, NAHC offers the following comments regarding the design and operation of the HHGM. The proposed new model would dramatically impact home health agencies (HHA) across the country as the current model has existed in its essential form since the inception of the Home Health Prospective Payment System (HHPPS) in 2000. There have been minor adjustments in the case mix adjustment model over that term, but the basic design of HHPPS has been virtually unchanged. Even if the new model is implemented in a rate neutral manner, the redistributive impact of payments will be highly disruptive. Many HHAs have developed business operations to correlate with the current payment model in terms of staffing expertise, health system integrations, care pathways, technology adoption, referral relationships, and financial budgeting.

The longstanding 60-day episodic payment model would be replaced with a 30 day payment “period.” The 153 payment group case mix adjuster model would be replaced with a 144 payment grouping model with significant changes in the adjuster’s inputs. This model itself is distinct from that originally devised by the CMS contractor, Abt Associates, and unveiled for the first time to the home care community in a Technical Report issued in December 2016. <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>

One notable and significant change from the current model would be the elimination of the “Utilization Domain” component of the HHPPS patient grouper model, That domain element adjusted payment amounts based on the number of therapy visits in an episode. CMS has argued for many years that the use of a Utilization Domain based on therapy visit volume was necessary

to achieve a sufficient level of “explanatory power” in the case mix adjustment and grouper model.

CMS posits that the purposes of the potential system changes are several including:

1. Eliminate the incentives for overutilization of therapy services
2. Recognize the resources use/cost of care to patients with complex needs
3. Improve accuracy of the payment in relation to cost.

A change of the nature contemplated with HHGM requires not only full transparency by CMS. It must also occur only through full participation of the HHA community as true expertise lies therein. In addition, no change of this magnitude should be instituted without a validation of the reliability of the new model. That validation necessitates a trial of the system as the means to determine the impact on care access and quality, HHA and other health provider behavioral change, and accuracy of payment distribution in a rate neutral manner. CMS has not tested this new model. Further, CMS has involved home health stakeholders, but has done so in ways that falls short of the level that can result in an acceptable payment system.

There are numerous structural elements that must be developed in any payment model. The NPRM, for the first time in the development and evolution of the new model, offers disclosure as to system elements that are crucial to the payment model operation. Neither the earlier Abt Technical Report nor the CMS webinar in January 2017 revealed anything about most of these elements. Instead, CMS only focused only on the case mix adjustment component while alluding to potential modifications of the existing HHPPS architecture. A reform of the case mix model can be done within the existing HHPPS structure. With the exception of the proposal to apply a 30-day payment period, the comments below address the design elements that appear for the first time in the NPRM.

A. 30-Day Payment Period

At the heart of the proposed payment system reforms is the replacement of the 60-day episode of payment with a 30-day payment period. Ostensibly, CMS contends that a 30-day payment period approach fits better given that a number of episodes of care are completed within 30 days or less. NAHC is concerned that CMS has not explored the pros and cons of continuing a 60-day episode of payment with the new patient classification model and, as a result, may be adding complexity and confusion in the home health benefit. While it is preferable to design a payment system that best aligns payment amounts with resource use, the benefits in using of a 30-day payment period must be thoroughly evaluated based on the standards employed in the

Medicare home health benefit as a whole rather than in isolation based on its explanatory power in a payment model.

The CMS proposal to shift to a 30-day payment period must be evaluated in light of the fact that:

1. A patient plan of care covers 60 days of service
2. The physician certification of an individual's eligibility for the home health benefit encompasses 60 days
3. The patient assessment, OASIS, that is used for many purposes including the assignment within the grouping model, is performed every 60 days

In addition, the inconsistency between a 30-day and a 60 day period that is applied in virtually all other aspects of the benefit must be considered in combination with the increased administrative burden and cost that would occur in doubling the number of claim submissions. The burden of claim submissions is not just the submission itself. With every claim submission, an HHA must secure all relevant patient records from the physicians and other care providers, secure appropriately signed and dated change orders from physicians, validate the data included in a billing such as the type, number of visits, time increments of visits, and the coding accuracy. These are all costly parts of the Medicare benefit process that are likely to be more efficiently handled with 60-day period billing than with a 30-day standard. In most instances, a 30-day period doubles the time spent on these tasks. The NPRM offers no such evaluation of the regulatory options regarding the payment period. Most importantly, the NPRM does not address whether the same case mix adjustment model can be equally or nearly as effectively in a 60-day format.

In discussions with CMS officials, NAHC is left with the impression that the 30-day payment period brings the home health benefit into conformity with other Medicare benefits. However, while other providers may operate within a 30-day billing cycle, none of the other benefits use a 30-day bundled payment model. There is a significant difference between a billing cycle and a bundled payment period. Further, providers use a 30-day billing cycle only when patients remain on services past the 30 day point. Otherwise, billings occur upon patient discharge. That occurs in home health services as well as other care sectors.

NAHC has also heard criticism of the current 60-day model such as that it pays for care when no care is provided where patients are discharged earlier than 60 days. However, that is a fallacy as the current model is tied to the resources used by patients within each of the 153 case mix categories regardless as to whether the patient is or is not discharged in advance of 60

calendar days. For example, the case mix weight used as a multiplier with the base rate reflects resource use over the full 60 days and when the patient is discharged earlier than the 60th day..

RECOMMENDATION: CMS should fully evaluate the benefits and burdens of shifting to a 30-day payment period as a replacement for the longstanding 60-day episodic payment that is consistent with all other administrative elements of the home health benefit. In addition, CMS should evaluate whether continuing a 60-day episodic payment model with the proposed patient classification system achieves an acceptable level of explanatory power (R squared) in comparison to a 30-day payment period approach.

B. Request for Anticipated Payment (RAP):

CMS proposes to continue the RAP concept in the new model, but in a revised form. The RAP was devised to protect the financial viability of an HHA through the provision of a cash flow system that provides some level of financial support as HHAs incur costs in a 60-day episode of care where billing and final payment is not made until the full episode costs are incurred. With HHGM, CMS proposes to continue the RAP with 60% of anticipated payment made on the initial 30-day period, 40% for the next 30-day period, and 50% for the initial subsequent period.

Many HHAs are small and do not have the financial resources to float their up-front expenses. Agencies invest thousands of dollars in staffing and supplies. Without a RAP, the earliest an HHA would receive payment would likely be 45 days following the start of a period if a claim is immediately submitted after the close of the period as there is a mandated 14-day payment delay. However, it more likely that the time period well beyond 45 days given the need to secure all the care documentation from certifying physicians as well as within the HHA staff. It is estimated that the average time from start of the payment period to the receipt of payment from Medicare can be expected to be 75 days based on experiences across the HHA community.

The amount of costs incurred during the first 30-day care period can well exceed \$3000 with an average cost of an estimated \$1800. HHA patients with care needs beyond a single 30-day period would lead to costs incurred as much as \$6000 prior to payment of the first care period. With an average financial margin of 1.95% based on total revenue and costs, an HHA is not in a financial position to carry the cost of care for 30 days, let alone for 75 days.

There is no efficiency achieved in billing on a 30-day cycle. Current RAP billing is a simple automated process unlike the final billing that requires numerous and fully compliant physician and HHA documentation to be in hand. HHAs would also need to continue billing daily/weekly since the 30-day period is different for every patient. There is no material efficiency achieved.

RECOMMENDATION: Maintain the RAP system. That system provides 60% of anticipated payment for the first 60 days and 50% of anticipated episodic payment thereafter for patients who remain on service. CMS has not experienced operational or program integrity concerns resulting from RAPs. HHAs operate on thin margins that do not provide the capital needed to carry multiple weeks of care costs without reimbursement.

C. Low Utilization Payment Adjustment (LUPA):

The NPRM maintains a LUPA system, but modifies it significantly. A LUPA will be based on a 30-day period with a minimum threshold of two visits before a full payment period amount would be payable. The case mix category-specific threshold would be set at the 10th percentile value of visits, leading to a threshold as high as 7 visits in a 30-day period where the HHA would be paid on a per visit basis.

Applying varying LUPA thresholds is not only confusing to Medicare HHAs, it raises the risk of inaccurate payment as behavioral changes dominate actions. The simplicity of the single LUPA threshold has worked well for over 16 years with very limited abuses. In addition, LUPAs have consistently underpaid for the cost of care. By adding multiple LUPA thresholds, the underpayments are likely to be increased.

RECOMMENDATION: Maintain the use of a single LUPA threshold. As an alternative, distinct LUPA thresholds for the first 30-day payment period and later periods might be worthy of exploration. At a minimum, the LUPA threshold options should be fully evaluated for potential impact, including behavioral change that could affect patient access.

D. PEPs (Partial; Episode Payment):

CMS proposes to maintain the PEPs in the new model. Currently, a PEP is made where a patient is transferred to another HHA prior to the completion of a 60-day episode.

PEPs are no longer needed in a 30-day period. PEPs make sense with a 60-day episode, since a provider should not receive a full 60-day episode when the patient with a continuing care need is discharged much earlier. However, with a 30-day period, the threat of an unjust payment is much less since the period is so much shorter. PEPs have been confusing as an HHA that discharges a patient with goals met can suffer a PEP when another HHA initiates care within the episode timeframe. With inpatient hospital services, partial payment relates to a patient's care need not the length of stay.

RECOMMENDATION: If a 30-day period replaces a 60-day episode unit of payment, PEPs should be eliminated and the initial HHA should receive payment consistent with the payment model without regard to the timing in which a second HHA assumes care..

E. Outliers:

CMS proposes to maintain an outlier payment using the same formula as under the current HHPPS with an adjustable Fixed Dollar Loss ratio and an 80% shared loss. Outliers are intended to provide payment in unique, high cost cases. Most PPS systems use one form or another of outlier payment. Outlier payment protects HHAs that serve abnormally high cost patients. Even with a 30-day payment period, the cost range can be extensive in each patient classification.

RECOMMENDATION: Develop a cost outlier model comparable to the existing system, but with standards tailored to the changed payment period.

F. Non-Routine Supplies (NRS):

The HHGM model proposes to incorporate NRS into the 30-day period payment rate. Current reimbursement for NRS is separate. Original HHPPS had an incorporated payment for NRS into the episode rate. However, CMS agreed with industry recommendations to separate out NRS using a 5-level case mix adjustment model. CMS notes that two-thirds of the NRS has a payment where there are no additional supplies. NRS needs and costs can vary greatly. In some circumstances, the NRS costs far exceed direct care costs, e.g. some wound care patients. A unique, patient specific NRS payment is consistent with the concept that prospective payment should try to reflect the cost of care for individual patients. Reliance on a bundled payment

model that incorporates the cost of NRS is highly likely to result in overpaying on many care periods and significantly underpaying on some.

RECOMMENDATIONS: Unless CMS can devise a patient classification model that fairly incorporates patient-specific NRS into the cost analysis, a separate manner of reimbursing NRS costs should be maintained. The HHGM proposal does not do such and instead bundles NRS into the case mix adjuster without consideration of patient-specific cost variations. Note that this recommendation is not intended to infer that the current 5-level NRS model should continue. Instead, we recommend that that CMS needs to thoroughly evaluate that model and any alternatives to determine which approach results in the most accurate reimbursement.

G. Other structural issues that must be considered:

The above referenced structural considerations are essential elements of any change from HHPPS to HHGM that would be triggered by a shift to a 30-day payment period. Below is a list of additional structural issues that must be addressed, each representing matters of significant importance to the day-to-day operation of the home health payment model.

1. How is an intervening hospice election/return to home health included in the model?
2. What are the standards for subsequent case mix weight recalibrations (nature and timing) as the new model is likely to need early refinements?
3. What is the methodology for allocating home health spending to the Medicare Part A spending vs. Part B spending?
4. How does the new model impact delivery and payment innovations such as BPCI Models 2 and 3 that were bid under the existing payment model?

SYSTEM INCENTIVES and IMPACTS

Payment models invariably create incentives and disincentives that affect provider behavior relative to patient acceptance, patient discrimination, care patterns, and resources applied to care. The impact of HHGM must be considered in that regard and measures employed to minimize unintended behavioral changes. Still, as is explained above, any significant cut in payment rates affects HHA behavior by reducing overall patient volume to minimize losses..

The system incentives and disincentives will also impact patients, the Medicare program, and other providers of services. Past experiences with more minor changes in the case mix adjustment model led to quick and broad behavioral changes. CMS needs to fully recognize and incorporate the lessons learned from other home health payment system changes in any advance of instituting HHGM or any other significant payment model reforms.. The behaviors stemming

from incentives and disincentives need to be addressed in the model design and program safeguards.

Here are a few of the more notable incentives, disincentives, and anticipated impacts that must be considered:

A. Incentives and Disincentives

1. **Discharge Timing:** The HHGM appears to incent patient discharge at or before 30 days along with significantly reducing length of stay or visits in the first 30 days. Such discharges can be premature raising concern for patients and Medicare spending on later care needs. The NPRM assumes there is a risk of extended care rather than early discharge. NAHC disagrees with that assessment.
2. **Discharge Timing:** An alternative to premature discharge is the incentive to keep patients on into a second 30 day period provided the financial value exists. NAHC believes that this risk is low given the intense oversight applied in home health services. Nevertheless, CMS must prepare for this potential reaction. As noted earlier, the risk is counter to past behavior where rates are reduced. .
3. **Referral Source:** The HHGM pays a higher rate for patients admitted from an inpatient stay. This may result in unnecessary inpatient admissions or access roadblocks for the community admissions. In addition, with an increasing focus on pre-hospital clinical interventions, there would be a disincentive for innovative HHAs to admit chronic care, co-morbid patients with community physicians to reduce inpatient admissions. Inpatient settings would become the primary patient referral target and community referral sources may find a less enthusiastic HHA community. In the end, a benefit redefinition results through a change in the financial system rather than an actual change in the scope of the home health benefit..
4. **Therapy Utilization:** While eliminating the therapy utilization domain that dominates the current HHPPS grouper model, shifting to other service utilization proxies could shift patients away from restorative therapies and encourage care planning that incentivizes patient dependency on nursing and home health aide supports. This could ultimately increase overall Medicare costs as well as a home health length of stay.

5. Regression Analysis: As is usual in changes to case mix adjustment models, CMS relies on a regression analysis to set case mix weights. However, such an approach would institutionalize any practices that are in violation of the Medicare standards for coverage. For example, CMS recently took steps to rectify contractor errors in rejecting claims for coverage of maintenance therapy and skilled nursing services for patients who did not show or have the potential for improvement. Patients with chronic conditions such as MS, ALS, Rheumatoid Arthritis, and other neurological/musculatal-skeletal conditions were affected by application of illegal coverage standards. By relying upon 2013 patient data in constructing HHGM, CMS provides a barrier to inclusion of these patients in the future. CMS must secure remedies within both the coverage standards and the payment model if it is to be compliant with Medicare law on the scope of benefits.

B. Patient impact

In any patient grouping model, reducing payment rates to some patient categories will likely impact such patients' access to care and the level of care provided because of financial considerations. Community patients and those with extended chronic needs are likely victims of HHGM.

Behavioral health patients are also a vulnerable group within HPPS and HHGM. The Abt technical report appears to conclude that behavioral health patients do not have complex and costly conditions. However, behavioral health patients often require longer visit time and much more coordination after the visit to assure the patient's needs are met by informal caregivers and other sources of care. The simulated HHGM model reflects a significant reduction in reimbursement for this type patient which is concerning as they are already receiving very low payment. Access risks will be high.

C. Impact on HHAs

1. Institutional/Community referrals – Reduction of payment for HHAs that admit referrals from the community is likely to trigger changes in business models that will reduce an HHAs patient volume, thereby raising the costs of a unit of care.
2. LUPA - Now, a LUPA is any patient who has fewer than 5 visits in a 60 day episode. In the new payment model, a LUPA will occur from 2-7 visits, depending on the patient, in a 30 day billing period. This means that more patients will be LUPAs, resulting in a significant payment reduction. In a number of cases, an HHA will receive two LUPAs in a 60-day period for a patient who would have brought a full episode payment. At the same time, it appears that certain LUPA patients may be

more profitable than non-LUPAs. These consequences will be highly disruptive of care practice, staffing assignments, and staffing makeup.

3. Therapy - The elimination of the Utilization Domain can be expected to reduce demand for therapy services and increase demand for nursing services. Such changes will force staffing reductions related to therapy and increased nursing hiring at a time when shortages continue.

COST INCREASE UNDER HHGM MUST BE ADDRESSED

Any reform must consider the impact on unit cost, overhead costs, cost timing, and implementation and maintenance costs of a new system model. These changed costs with HHGM will include the following:

1. New IT systems will be needed. This cost is significant.
2. Increased costs related to training staff on how HHGM works and what changes in HHA operations it generates. Additional training on use of revised IT systems under new system will also be need. NAHC experts estimate the time cost at 3 to 4 hours per person plus cost of trainers.
3. Increased costs related to billing every 30 days rather than 60 days, including costs of staff tracking and collecting more frequently signed physician orders.
4. Increased interest costs on working capital borrowing related to cash flow decline with modified RAP's.
5. An increase in the number of billings will translate to an increase in the number of claims subject to ADRs and other reviews necessitating added staff to respond.
6. Potential losses due to inadequate reimbursement for non-routine supplies due to potential flaws in developing those costs to be included in 30-day payment period reimbursement
7. Increased staff to monitor LUPA levels that will be varied by diagnosis and grouping instead of a standard less than 5 visits.

RECOMMENDATIONS:

CMS should adjust reimbursement rates to cover the added costs triggered by HHGM.

B. Proposed Updates to the Home Health Care Quality Reporting Program (HH QRP) Home Health Quality Reporting Program

Accounting for Social Risk Factors in the HH QRP

NAHC supports and appreciates CMS' efforts to include social risk factors in the HHQRP. NAHC recommends including education and community support systems to the list of social risk factors.

Proposed Data Elements for Removal From OASIS

The list of the assessment items proposed for removal are not used in the calculation of quality measures, payment, survey, the home health value based purchasing model, or care planning. These changes in the OASIS would result in the collection of 247 fewer data elements at specific time points within a home health episode. However, CMS proposes to add 17 new assessment items, with collection of 270 data elements at specific time points (See [Attachment B](#)).

Additionally, CMS estimates a decrease in cost of \$3,700.74 per HHA annually related to the proposed changes in the HHQRP

NAHC is concerned that the assessment items proposed to be added will likely cause more burden for home health agencies to collect than those that are proposed to be removed since they are new assessment items. CMS has significantly underestimated the cost associate with the proposed changes to the OASIS assessment and the HHQRP. Any time significant changes are made to the OASIS assessment, such as those in the proposed rule, the burden for agencies is great. Burden includes time and costs required for staff training, data set changes, and the opportunity cost associate with the learning curve needed to achieve competence in completing new assessment items.

NAHC anticipates that it will take much of 2018 for CMS to finalize the proposed changes and develop and issue a revised OASIS assessment instrument. Therefore, agencies will not have sufficient time to prepare for implementation by January 2019.

Recommendations: CMS should provide home health agencies at least one year to implement the OASIS when significant changes are made to the data set. In addition, stakeholder outreach and training should be provided during the year prior to implementation.

HH QRP Quality Measures Proposed Beginning With the CY 2020 HH QRP

- **Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function” (NQF #2631).**

CMS plans to add functional and mobility assessment items for a new cross setting functional quality measure and as standardized assessment items to meet the IMPACT Act requirements. The standardized assessment items to be collected for these functional domains include 7 self-care activity items and 17 mobility items. The quality measure is a process measure that uses a subset of the proposed standardized assessment items. In reviewing the proposed functional assessment items the most notable aspect of the data set is the number of items the agency will be required to complete; there are a total of 24 assessment items.

Additionally, CMS proposed to maintain the following functional assessment items currently collected on the OASIS assessment tool.

- M01810 Current Ability to Dress Upper Body
- M01820 Current Ability to Dress lower Body
- M01830 Bathing
- M01840 Toilet Transferring
- M01848 Toilet Hygiene
- M01850 Transferring
- M01870 Feeding and Eating

The measure developers maintain that the above assessment items are not duplicative because “...differences include: (1) the data collection and associated data collection instructions; (2) the rating scales used to score a patient’s level of independence; and (3) the item definitions” NAHC disagrees with the assertion that the two data sets do not cause duplication. Although the assessment items might assess function in a slightly different manner, they still assess many of the same self-care and mobility activities, hence redundancy in data collection. Requiring that agencies collect two sets of data to assess functional status creates additional burden without any added benefit.

Furthermore, the proposed standardized assessment items have an assessment period of three days. This time frame does not align with the five-day window home health agencies have to complete the OASIS assessment. Agencies will be required to complete these assessment items within three days while the remainder of the OASIS items can be completed within five days.

Recommendation: Delay adopting the Application of Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) measure for home health agencies until such time that redundancy for function and mobility can be removed from the OASIS assessment instrument and the time frame for collection is aligned with five-day OASIS assessment collection time frame. In the meantime, CMS could use OASIS assessment item GG0170C Functional Abilities and Goals to satisfy the requirements of the IMPACT ACT for a standardized functional assessment item and cross setting measure for function.

- **Application of Percent of Residents Experiencing One or More Falls with Major Injury**

CMS is proposing a new quality measure titled Application of Percent of Residents Experiencing One or More Falls with Major Injury. Major injury is defined as bone fractures, joint dislocation and closed head injuries with altered consciousness or subdural hematoma.

The main concern with the falls with major injury measure is that it is not risk adjusted. Although an unadjusted falls measure could provide valuable information regarding the overall rates of falls occurring within the agency, it has limited value when comparisons are made to other home health agencies or other post-acute care (PAC) providers.

The measure developers in their response to an October, 2016 call for public comments on this falls measure rejected the request for risk adjustment claiming that falls with major injury are considered a “ never event.” Although this position might make sense for institutionalized patients, it does not take into consideration the uniqueness of the home health setting. NAHC still believes a request for CMS to risk adjust this measure is warranted.

Home health agencies provide intermittent care to patients with varying care needs, living environments and caregiver support. Agencies have limited control over a patient/caregiver’s ability or willingness to comply with fall prevention strategies. Additionally, home health patients are permitted to leave the home infrequently or for short duration, and are allowed unlimited absences for medical reasons. Therefore, a home health patient could encounter fall risks for which the agency could not be expected to mitigate.

Without risk adjustment, the measure could present a distorted correlation between the rate of major injuries related to falls and the quality of care provided by the agency, and as previously mentioned, has limitations when making comparisons among home health agencies. Concerns over the inclusion of the measure into CMS’ public reporting system, and potentially in a home health value based purchasing program, could result in agencies avoiding caring for patients perceived as high risk for falls.

Of equal concern is that the IMPACT Act requires the falls with major injury measure to be applied across other PAC settings; all of which are facility based with 24/7 supervision and

the ability to affect fall prevention through direct interventions by the facility staff. The standard for fall risks and prevention that is applied to facility based care cannot be applied to community care settings.

Recommendation: CMS could include an unadjusted rate for falls with major injury on the agency's confidential feedback reports along with a risk adjusted rate for the measure. This will allow the agency to see their actual fall rates while risk-adjusted rates could be used for public reporting and when compared to other PAC settings.

Proposed Standardized Patient Assessment Data

- **Cognitive function and mental status**

CMS proposes to add three new assessment items to address the IMPACT Act domain for cognition and mental status.

1. Brief Interview for Mental Status (BIMS)
2. The Confusion Assessment Method (CAM)
3. Behavior Signs and Symptoms

The BIMS is a nine-question item that assesses cognition through repetition and recall with and without prompting, and temporal orientation. The CAM is a six-question item that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment.

The Behavior Signs and Symptoms assessment item consists of three questions that assess whether the patient has exhibited any behavioral symptoms that may indicate cognitive impairment or other mental health problem including physical, verbal, and other disruptive or dangerous behavioral symptoms.

There is concern that the BIMS and CAM screens are not best practice for use in home health because they weren't designed for the home health setting and require specialized training to accurately administer. Any assessment tool, particularly when it is being used to score a patient's status and determine eligibility for services, payment and data collection for future decision making, needs to be carefully chosen for the right setting.

Additionally, CMS is proposing to add all three items to the OASIS data set. In total this would add 18 assessment items. CMS is not proposing to remove the current OASIS items that assess cognition (M01740) and behavior (M01745). The inclusion of the three proposed

assessment items for cognition and behavior seems unnecessary and duplicative; creating additional burden for data collection without any added benefit.

Recommendations: CMS should re-evaluate the proposed items for their suitability in the home health setting and develop a more streamlined data set with fewer items than what is proposed. Additionally, CMS must consider duplication in data collection if any of the proposed assessment items are added to the OASIS assessment instrument.

- **Special Services, Treatments, and Interventions**

CMS proposed to add 15 service, treatment, and intervention categories that total 29 assessment items to capture which services, treatments and/or interventions the patient is receiving. The number of items proposed for this standardized assessment domain seems excessive and duplicates an existing OASIS assessment item. Several of the proposed assessment items overlap with the OASIS assessment item M1030-Therapies the patient receives. M1030 captures patients receiving intravenous therapy, parenteral nutrition, and enteral nutrition.

Recommendation: CMS should limit the list of items to reduce burden and duplication. CMS could select a few of the proposed items that do not overlap with items currently collected on the OASIS to meet the requirement of IMPACT Act for this domain.

C. Input Sought for Data Reporting Related to Assessment Based Measures

CMS proposes to expand the population for quality measurement to include all patients served by the home health agency. This would require agencies to collect and report OASIS data on all patients.

HHAs remain concerned with the additional burdens associated with collecting OASIS assessment items on non-Medicare/non-Medicaid patients; both in terms of the increased burden for staff and the cost to collect the information. Agencies will not likely be reimbursed by private pay sources to cover these costs.

CMS' claim that there is burden associated with having separate assessments for private pay patients is misguided. Agencies that choose to develop separate assessments for private pay patients do so to avoid the burden associated with collecting the OASIS items.

Additionally, CMS has not provided sufficient information to support their need for the OASIS assessment information on private pay patients. However, NAHC does not believe CMS has such a need as to justify the collection and reporting to CMS assessment information on patients whose services will not be paid by Medicare or Medicaid.

Furthermore, the home health Conditions of Participation (HHCOPs) apply to all patients regardless of payer to ensure the same quality of care is provided to all patients served by the HHA.

Recommendation: CMS should maintain the current requirement to exclude non-Medicare and non-Medicaid patients from the OASIS collection.

D. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

CMS is seeking feedback on developing a within-stay potentially preventable hospitalization claims based measure. The potentially preventable within-stay hospitalization measure would look at the percentage of HH episodes in which patients were admitted to an acute care hospital or seen in an emergency department for a potentially preventable condition during an HH episode.

Although NAHC could support a within-stay re-hospitalization measure, NAHC has concerns regarding including another hospitalization measure to the four measures that currently report hospitalizations, re-hospitalizations, and emergency department (ED) use on home health patients (see below).

- Acute Care Hospitalization (OASIS based)/ Emergency Department Use with Hospitalization (OASIS based)/
- Acute Care Hospitalization During the First 60 Days of Home Health (Claims-based)/ Emergency Department Use without Hospitalization During the First 60 days of Home Health (Claims-based)

- Rehospitalization During the First 30 Days of Home Health (Claims-based)/Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (Claims-based)
- Potentially Preventable 30-Day Post-Discharge Readmission Measure (Claims based)

CMS does not provide sufficient information to support the need for five hospitalization measures on home health patients.

Recommendation: CMS should eliminate several of the above hospitalization/ED use measures prior to requiring that a within-stay re-hospitalization and ED use measure be collected and reported on home health patients.

E. CMS Request for Information on CMS Flexibilities and Efficiencies

1. Revise physician documentation and certification requirements in the Medicare home health benefit

42 CFR 424.22(c)

Medicare rules require that the physician certification of home health eligibility be fully supported solely on the basis of the records within the certifying physician's record. The certifying physician can rely upon records from other providers and practitioners, including the home health agency, but only if the physician records indicate a specific written acknowledgement by the physician that these records were considered by the physician in determining whether to certify eligibility. CMS recognizes that the non-physician records are very useful in accurately determining a patient's eligibility for coverage, but continues to maintain a highly burdensome and confusing requirement on what it takes to have non-physician records be part of the eligibility evaluation. When considering the whole record of a patient, the

accuracy and integrity of the eligibility is exponentially improved. CMS should eliminate its burdensome, paperwork focused standard that leads to erroneous claim determinations.

Recommendation: CMS should revise 42 CFR 424.22(c) to provide that the patient records of a home health agency are automatically considered when determining eligibility provided that the records are used to supplement or clarify consistent physician records.

2. Revise Home Health Conditions for Participation

Revisions to the HHCOPs are estimated to have a total cost of \$290.3 million in the first year and \$290 million the second year and thereafter. This is the first complete revision of the HHCOPs in over 30 years. In addition to the burden associated with revising policies, processes and operations in order to comply with the requirements, the burden is compounded by the lack of guidance materials available to home health agencies. Agencies are to implement the revised requirements based on their individual interpretations of compliance expectations. Additional modification to policies, processes and operations will need to be made if the agency has not applied the revised HHCOPs in accord with CMS' intentions.

HHAs are requesting that the revised HHCOPs not be implemented until at least six months after the interpretive guidelines are issued and that CMS seek stakeholder input during the development of these guidelines.

In addition to general concerns with the burden of the revised HHCOPs, following are specific requirements that if modified would provide significant relief for HHAs.

42 CFR 484.50(a)(3)

(a) Standard: Notice of rights

(3) Provide verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary, no later than the completion of the second visit from a skilled professional as described in § 484.75.

The requirement to provide the patient verbal notice in addition to written notice in a language and manner that the patient understands creates an additional burden since the agency must ensure a written notice has been provided prior to the initiation of care in a language that the

patient/legal representative understands. The verbal notice must be provided by the second skilled visit, which in most cases will be the next day.

Recommendation: Do not require verbal notice be provided in addition to the written notice. The agency should be permitted to use their discretion as to when verbal notice is required.

42 CFR 484.50(a)(4)

(4) Provide written notice of the patient's rights and responsibilities under this rule and the HHA's transfer and discharge policies as set forth in paragraph (d) of this section to a patient selected representative within 4 business days of the initial evaluation visit.

The requirement that the patient selected representative must also be provided with written notice within 4 days of the evaluation is a burden and a mandate for the agency that should be required only at the request of the patient.

Recommendation: Require the agency provide the patient-selected representative with written notice at the patient's request.

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42 CFR 484.50(c)(8) Standard: Rights of the patient. The patient has the right to—

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

Recommendations: Limit written notice requirements of reduced/terminated services to Medicare patients in accord with advanced beneficiary notice requirements (ABN) and the Home Health. The ABN and Home Health Change of Care Notice are specific to Medicare Fee for Service patients and do not extend to all patients

42 CFR 484.50(a)(10)

(10) Be advised of the names, addresses, and telephone numbers of the following Federally-funded and state-funded entities that serve the area where the patient resides:

(i) Agency on Aging,

- (ii) Center for Independent Living,
- (iii) Protection and Advocacy Agency,
- (iv) Aging and Disability Resource Center; and
- (v) Quality Improvement Organization

Recommendations: Require home health agencies to provide the patient with the name, address, and telephone number of only one appropriate consumer protection agency serving the geographic region.

42 CFR 484.55(a)(1)and(b)(2).

(a) Standard: Initial assessment visit. (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

**(b) Standard: Completion of the comprehensive assessment. **

(1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

In many instances in order to comply with this requirement the agency must provide additional non-billable RN visits to complete the initial and comprehensive assessment.

Currently, a therapist may conduct the initial and comprehensive assessment if therapy is the only discipline ordered. Therefore, there has always been precedent for a therapist to conduct the initial and comprehensive assessments

Recommendation: Permit either the RN or therapist to conduct the initial evaluation visit and comprehensive assessment, as required by the plan of care (POC) when both disciplines are ordered at the start of care.

42 CFR 484.60(e) Standard: Written information to the patient. The HHA must provide the patient and caregiver with a copy of written instructions outlining:

- (1) Visit schedule, including frequency of visits by HHA personnel and personnel acting on behalf of the HHA.
- (2) Patient medication schedule/ instructions, including: medication name, dosage and frequency and which medications will be administered by HHA personnel and personnel acting on behalf of the HHA.
- (3) Any treatments to be administered by HHA personnel and personnel acting on behalf of the HHA, including therapy services.
- (4) Any other pertinent instruction related to the patient's care and treatments that the HHA will provide, specific to the patient's care needs.
- (5) Name and contact information of the HHA clinical manager.

CMS in the proposed rule chose not to finalize a requirement that the agency provide the patient with a copy of the POC. The requirement was not finalized mainly due to concerns by HHAs over the burden associated with providing this information to all patients. The requirement under §484.60(e) is essentially the same information as in the POC and would present the same kind of burden especially if written information regarding all treatments is expected to be provided. §484.60(e) was not issued in the proposed rule but added in the final rule for the HHCoPs, therefore, there was not an opportunity for public comment on this requirement.

CMS allows for one or more clinical manager. Which clinical manager will be assigned to the patient may not be known at the time the information is provided or may change. The agency is required under §484.50 (a) to provide the contact information of the administrator which should be sufficient assurance that contact information of appropriate agency personnel is provided to the patient/caregiver.

Recommendation: Limit the information provided to the visit frequency by each discipline (not visit schedules), medication schedule and instructions, and any other pertinent instructions related to patient care needs as determined by the agency. Eliminate treatments to be administered and name and contact information of the clinical manager.

42CFR 484.105(f) Standard: Services furnished. (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

This requirement does not fit within the current health care service economy and workforce market. The "service directly requirement" is a proxy for establishing quality assurance in the provision of care. Medicare maintains an outdated and unfounded belief that an employed caregiver is more capable of providing high quality services to patients than a contracted caregiver. Arbitrary staffing/contractor ratios do not ensure quality of care. Existing and proposed quality, coordination, and supervision regulations and guidelines, if enforced, can serve to ensure quality of care to Medicare beneficiaries.

Recommendation:

HHAs should be permitted to provide unlimited services under arrangements both by individuals or other agencies or organizations. CMS should enforce the home health regulations that require oversight and control of services by the certified providers regardless of whether the persons providing care are employees or contractors.

42 CFR 484.110(e) Standard: Retrieval of clinical records. A patient's clinical record (whether hard copy or electronic form) must be made available to a patient, free of charge, upon request at the next home visit, or within 4 business days (whichever comes first).

The requirement at §484.110(e) does not provide sufficient time for agencies to produce a medical record in many cases. If the patient is scheduled to be seen by the agency the day after the request is made, the agency may have to copy, review, and deliver the record in less than 24 hours. Even a four day time frame is not sufficient for many agencies. It is not unusual for agencies to centralize requests and have a detailed process for review prior to releasing any protected health information. If the record is to be mailed, the agency will have only one or two days to reproduce the record, otherwise they will be out of compliance with time frame outlined in the standard.

CMS maintains that agencies will not incur any additional burden with the requirement since making clinical records available to the appropriate authority is part of the survey and

certification process. However, surveyors do not typically request archived records and are accustomed to viewing the active medical record using the agency's EHR; a very different process than having to reproduce and review a record that could be voluminous.

Additionally, the cost could be substantial depending on the size of the medical record. Home health agencies seem to be the only provider type that has such a requirement for responding to medical record requests.

Further, CMS did not propose a time frame for responding to medical record requests in the proposed rule, but added "at the next home visit, or within 4 business days (whichever comes first.)" in the final rule for the HHCOPs, therefore, there was not an opportunity for public comment on this requirement.

Recommendation: CMS should align §484.100(e) with the requirements of the Health Insurance Portability and Accountability Act at §164.524(b) (2). §164.524(b) (2) provides for 30 days for a health care entity to act upon on a request for a copy of the medical record. Also in accord with §164.524(c) (4), HHAs should be allowed to charge a cost based fee for the labor to copy the record, any required supplies, and postage, if applicable

42 CFR 484.80(b)(3)(ix)(B)

Standard: Content and duration of home health aide classroom and supervised practical training

.....

(3) A home health aide training program must address each of the following subject areas:

.....

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include—

.....

(B) Sponge, tub, and shower bath

(C) Hair Shampooing in sink, tub and bed

The requirement is for the aide to be competency trained/evaluated in performing personal hygiene and grooming tasks that include sponge, tub, and shower bath, and shampooing in sink, tub and bed, rather than the current requirement which allows competency training/evaluation in

a sponge, tub, or shower and hair shampooing in sink, tub or bed. Home health agencies are required to train/evaluate aides in activities for bathing and shampooing on a live patient. Home health patients typically do not bath in tubs due to safety and mobility concerns (i.e. falls and difficulty getting in and out of the tub). Under the current interpretive guidelines, CMS will not permit bathing and shampooing activities to be evaluated through simulation. If CMS takes the same position with the revised bathing and shampooing activities, the requirement will significantly delay competency evaluations and /or training while the agency locates patients for which the aide can be trained in all three bathing and shampooing methods.

Recommendation: Allow the bathing and shampooing activities to be competency trained/evaluated through simulation with a volunteer without requiring the volunteer to receive an actual tub bath or shampooing.

§484.60(a)(3) All patient care orders, including verbal orders, be recorded in the plan of care.

§484.60(c)(1) The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA must promptly alert the relevant physician(s) to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

Currently agencies will receive a verbal order, document the verbal order in the medical record, and send the order to the physician for signature. Under the new CoPs at §484.60(a)(c) those orders will be added directly to the plan of care. The frequency with which the physician must review and sign the revised plan of care is unclear. However, CMS has indicated that it expects agencies to send the POC to physician for signature each time a new order is added.

Recommendation:

Allow the agency to send the revised POC to the physician for review and signature at a frequency based on agency policy, but at least once every 60 days, in accord with §484.60(c)(1), as long as the agency is communicating the revisions to the physician and verbal orders are sent to the physician for signature as soon as possible.

For example, during the 60 day episode the patient has a verbal order for a medication change in the third week and a verbal order to decrease the SKN visit frequency in the seventh week. The plan of care is updated accordingly. The individual verbal orders are sent to the physician as they are received. The agency sends the revised plan of care reflecting those

orders in accord with agency policy, (which could be at recertification), to the responsible physician for signature.

CONCLUSION

Thank you for the opportunity to submit these comments. Please free to contact the undersigned if further information is needed.

Very Truly yours,



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