VNAA
Visiting Nurse Associations of America

August 26, 2016

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

RE: CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

Dear Acting Administrator Slavitt,

On behalf of the Visiting Nurse Associations of America (VNAA), thank you for the opportunity to comment on the 2017 Home Health Prospective Payment System proposed rule. VNAA advances quality, value and innovation in home-based care and represents mission-driven providers of home and community-based health care, including hospice, across the United States.

VNAA members provide high-quality, patient-centered care at home, as well as offer support for family caregivers. They primarily serve the most clinically complex and vulnerable patients[1], who are by definition homebound and who will benefit from having closely integrated health exchange between all members of the care team—regardless of the severity of their illness—and serve a mixture of Medicare, Medicaid, privately-insured and uninsured patients. Home health providers continue to provide value and innovation in home-based care and care coordination.

Home-based care providers work to improve the management of patients with chronic conditions, thus addressing some of the greatest challenges in health care today, including medication management, uncoordinated transitions of care and high rates of unnecessary hospital and emergency department utilization[2]. In addition, home health provides medically necessary, skilled services in an incredibly efficient manner, providing care at a fraction of the cost of institutional care.

In their March 2016 report, MedPAC notes that the volume of home health services has declined. And while the average number of episodes has increased, this rise coincides with a relative shift towards episodes not preceded by a hospitalization. Community-admitted users, of which about 40 percent are dual eligible, had a larger share of episodes with high numbers of visits (including from home health aids). This trend can be expected given the shift toward preventing and reducing primary hospitalization rates. To prevent primary hospitalizations and to keep beneficiaries in the least costly setting, an increase in the use of home health services is appropriate and desirable.

[1] Avalere analysis for AHHQI of the Medicare Current Beneficiary Survey, Access to Care file, 2013.

[2] *Managed Healthcare Executive's* 2015 State of the Industry Survey

VNAA urges CMS to more carefully and accurately measure access to home health services, and to move beyond the consideration of zip code coverage as a measure of "access to care." Access problems must always be defined in terms of patients who do not receive needed care rather than by the number of home health agencies reportedly operating in a specific postal zip code.

We acknowledge that access to home health is difficult to measure because patients who are eligible for Medicare home health services may also receive care in another, more intensive setting when home health services are not available. Access to home health care is limited whenever a homebound individual requires skilled care as ordered by a physician and yet is unable to access services and fully receive the Medicare home health benefit. An access problem is created when a beneficiary is unable to receive services because no agencies serve their specific neighborhood, no agency will accept the patient because they do not have sufficient staff to meet the patient's specific needs, or an agency has admission policies that discourage the admission of challenging, high-cost patients.

We strongly recommend that CMS consider other standards for access, including: provider to enrollee ratios; travel time; travel distance; appointment wait times; and number of providers accepting new patients, among others.

As such, VNAA expresses strong concern about the overall reduction in Medicare payment rates to home health agencies. If finalized, this proposal would dramatically impact VNAA member organizations and result in a reduction of $180 million to Medicare certified home health agencies nationwide in 2017. VNAA's nonprofit and mission-driven agencies provide high quality care in an efficient, streamlined manner. While CMS maintains that home health margins are high compared to an unspecified standard, the experience of our members is that Medicare payment rates underpay and do not reflect the real costs of serving vulnerable patients and maintaining a qualified, trained workforce. If this rule is finalized as proposed, VNAA is concerned that access barriers to home based care will emerge, as agencies shutter their doors. Our members believe that the illusion of high margins is created by outdated cost reporting regulations that force agencies to understate their costs both by refusing to recognize certain costs (such as telemonitoring) and encumber home health agencies with laborious documentation requirements for justifying costs that are concentrated in vulnerable populations (such as intensive case management, employee security, and patient non-compliance).

Home Health Pre-Claim Review Demonstration

VNAA continues to be greatly concerned and frustrated with the impending Pre-Claim Review Demonstration for Home Health Services. The changes from the Prior Authorization Demonstration for Home Health Services and the newly dubbed Pre-Claim Review Demonstration for Home Health Services are cosmetic, at best, and not of true substantive value. At its core, these changes grant ability for home health agencies to comply with the Conditions of Participation and begin care prior to Pre-Claim approval while remaining at risk of being denied payment as a result of poorly-implemented and inconsistently applied documentation requirements.

The Paperwork Reduction Act (PRA) notice used to implement the Pre-Claim Review demonstration notes as the justification for the demonstration "extensive evidence of fraud and abuse in the Medicare home health program, in particular, in the chosen demonstration states." VNAA supports a wide range of policies to combat waste, fraud and abuse, and our members are committed to improving the integrity of the Medicare home health program. VNAA has strongly endorsed home health moratoriums, outlier caps and other data-driven tools that are effective at stemming fraud in a targeted and direct manner. The HHS Office of the Inspector General recently identified five key characteristics for home health fraud[3]:

[3] Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases, 6/21/16, https://oig.hhs.gov/oei/reports/oei-05-16-00031.asp

- High percentage of episodes for which the beneficiary had no recent visits with the supervising physician
- High percentage of episodes that were not preceded by a hospital or nursing home stay
- High percentage of episodes with a primary diagnosis of diabetes or hypertension
- High percentage of beneficiaries with claims from multiple home health agencies (HHAs)
- High percentage of beneficiaries with multiple home health readmissions in a short period of time

Despite these clear and appropriate characteristics of fraudulent activity, Dr. Shantanu Agrawal, Deputy Administrator and Director of the CMS' Medicare Integrity Program Office, stated in his May 24, 2016 testimony before the U.S. House of Representatives Committee on Energy and Commerce that the majority of the 59 percent of improper payments were because of *poor or incomplete documentation*[4]. In the year prior to the start of Face-to-Face, the improper payment rate for home health care was about 17.3 percent for 2013 and following the implementation of Face-to-Face; 51.4 percent in 2014 and 59 percent in 2015.[5].

The Pre-Claim Review Demonstration is a blunt policy instrument that targets all providers and puts a disproportionate burden on good actors. At the same time, nothing in the Pre-Claim process will stop bad actors from submitting falsified claims; Pre-Claim programs have no mechanism to identify these bad actors. Ultimately, this demonstration will add little additional value in preventing fraud but will certainly result in improperly delayed or denied payments to agencies while giving CMS the ability to claim even higher numbers of "improper payments" due to "incomplete documentation."

The Pre-Claim Review Demonstration began in Illinois on August 3, 2016. Despite CMS' repeated and even profuse assurances of readiness , the demonstration was delayed by a few days, because procedures and administrative functions were not yet in place. . VNAA urgently requests that CMS quickly develop, clarify, implement and oversee responses to the following in the form of publicly posted Frequently Asked Questions and official guidance documents to providers, physicians and, most importantly, Medicare Administrative Contractors.

- Will there be opportunities for adjustments to the Pre-Claim review and documentation process, and if so, when?
- How will MACs ensure capacity to receive these Pre-Claim documents? Currently, home health providers have to fax Pre-Claim documents as the eService system with the MAC is not able to handle the documentation. Further, the HiTech Act was enacted, in part, to move forward with electronic health records (HER) and to better ensure HIPAA. The current processes available for Pre-Claim review are a step backwards. At this time, home health agencies with EHRs are frequently being forced to print forms and then scan and fax them for submission to submit the CMS MAC contractor, Palmetto. Members' EHR systems were not set up to print to PDF as that goes against those HiTech principles and thus require, printing, scanning and faxing. Anecdotally, a typical application is taking over twelve minutes to fax.
- How will CMS ensure general accountability of the Medicare Administrative Contractors (MACs) and provide satisfactory oversight to ensure consistency in application of requirements?
- When a MAC reviews a pre-claim submission, will it indicate all areas from the submission that do not meet "acceptance" or will there be multiple submissions for each pre-claim?
- What level of re-education will be conducted for the MACs? When will this education commence?
- What level of education will be done for physicians? When will this education commence?

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[4] Dr. Shantanu Agrawal 5/24/2016 U.S. House Energy and Commerce testimony quote "One area in Medicare fee-for-service on which we are focusing our efforts is in home health services, which have had particularly high improper payment rates in recent years, mainly due to documentation errors."

[5] Health and Human Services Supplementary Appendices for the Medicare Fee-for-Service Improper Payment Rate Report (2013, 2014 and 2015 editions)

- Will MACs have required response times to home health agencies that will vary by method of submission (e.g., on-line portal, fax, electronic submission of medical documentation (esMD), etc?)
- Will CMS provide electronic forms for use by referring physicians and receiving home health agencies to simplify the Pre-claim documentation process?
- Will home health agencies have the opportunity to be "whitelisted" or "provisionally approved" when they show compliance with Pre-claim documentation for a consistent and defined time period?"
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Update and Clarity About Improper Payments for Home Health Care

Repeatedly, the home health care industry is shamed by reports of 'improper payment rates' of about 17.3 percent for 2013 and, following the implementation of Face-to-Face; 51.4 percent in 2014 and 59 percent in 2015.[6] As was stated earlier in his May 24, 2016 testimony before the U.S. House of Representatives Committee on Energy and Commerce, Dr. Shantanu Agrawal, Deputy Administrator and Director of the CMS' Medicare Integrity Program Office stated that the majority of the 59 percent of improper payments were because of *poor or incomplete documentation*[7].

Through the adjudication of appeals, Administrative Law Judges (ALJ) are finding in favor of home health care providers in more than 83 percent of the cases[8] This lends credence to the belief that the bulk of the documentation errors are coming from confusion and lack of clarity from the MACs on CMS' behalf. On numerous occasions providers are experiencing conflicting guidance from the MACs, incomplete and down websites and erroneous decisions that are resulting in additional appeals to a system that is already faltering under the weight and number. According to HHS[9], a backlog exists of more than 800,000 appeals from health care providers challenging denied Medicare claims. That is about 10 times as many as the program can adjudicate in a year at its current funding levels.

VNAA demands that these 'improper payment rates' be updated to accurately reflects the true improper payment rates of home health care and not the over inflated number prior to adjudication.

Our specific comments on the rule follow.

HH PPS Payment Policy Provisions

CMS projects that Medicare payments to home health agencies in CY 2017 would be reduced by 1.0 percent, or $180 million based on the proposed policies.

VNAA Comment:

VNAA is deeply concerned about another negative payment adjustment. Additional payment reductions will be devastating to home health agencies and will impact access to critically needed services, safety net providers and the agencies who serve underserved regions and/or the most vulnerable beneficiaries. This inevitably reduces access to care in the very populations (underserved and minority) that HHS has identified as requiring better access to high quality care in their own communities.

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[6] Health and Human Services Supplementary Appendices for the Medicare Fee-for-Service Improper Payment Rate Report (2013, 2014 and 2015 editions)

[7] Dr. Shantanu Agrawal 5/24/2016 U.S. House Energy and Commerce testimony quote "One area in Medicare fee-for-service on which we are focusing our efforts is in home health services, which have had particularly high improper payment rates in recent years, mainly due to documentation errors."

[8] ALJ Disposition Data, FY2016 (9/26/15-7/29/16) accessed at https://www.ssa.gov/appeals/DataSets/03_ALJ_Disposition_Data.html

[9] http://www.modernhealthcare.com/article/20160209/NEWS/160209844

The cuts also fail to take into account the many other factors that are required to deliver and maintain high quality, patient-centered care. These costs include high labor and training costs and investments in health IT and staff training on health IT. Preparing for value-based purchasing requires significant investment in new infrastructure. Providers must acquire/update data systems and analytics, invest in connections to community partners, build business acumen through talent recruitment and training, and develop and deploy evidence-based clinical guidelines, among other infrastructure. CMS' experience with other value-based purchasing initiatives demonstrates the need for these investments during the period of transition. Across the board cuts have the unintended but inevitable effect of reducing investment in infrastructure and thus compromise the future viability of safety net providers.

The cost of these investments will vary by provider as some will have certain elements already in place, while others will be building from scratch. Relatively few, if any, home health providers will be prepared using solely their existing infrastructure. While other provider types received financial assistance to build certain types of capacity (e.g., meaningful use incentive dollars for the acquisition and use of electronic health records), home health providers have not received similar assistance. Cutting rates to the extent proposed will essentially ensure that home health providers cannot be successful in the proposed value-based purchasing program or other healthcare system transformation efforts.

CMS should entirely revise this section of the proposed rule and instead include a policy that includes appropriate and positive reimbursement for home health providers. It should adopt anapproach to payment adjustments that encourages rather than discourages investment by safety net providers.

CY 2017 is the final year of the four-year phase-in of the rebasing adjustments to the HH PPS payment rates. As finalized in the CY 2014 final rule, the CY 2017 rebasing adjustment to the national, standardized 60-day payment rate is -$80.95. The overall impact due to the rebasing adjustments is estimated to be a -2.3 percent decrease in HH PPS payments for CY 2017.

CMS will implement a 0.97 percent reduction to the national, standardized 60-day episode rate in CY 2017 to account for nominal case-mix growth from 2012 to 2014 (prior to rebasing). CY 2017 will be the second year of the three-year phase-in of the reduction to account for nominal case-mix growth. CMS continues to phase in the last year of the rebasing cut and adds a duplicative phase-in of a cut for case mix creep aka "nominal average case mix increase."

VNAA Comment:

VNAA has continuously objected to the four-year phase-in of rebasing. CMS' reliance on earlier legislative authority to justify dramatic reductions is a contradiction of the authority granted to CMS by Congress.. VNAA has urged CMS to adhere to the limits on home health rate cuts established by Congress. As such, we maintain that CMS should not implement the full final year cut under rebasing.

In addition, since this is the end of the rebasing period, CMS should wait until current year data is available, evaluate the impact of the rebasing adjustments using current data, and consult with Congress before considering the additional reductions or further rebasing as suggested by the Medicare Payment Advisory Commission (MedPAC).

VNAA is dismayed that CMS continues to pursue implementation of the inherently flawed nominal case-mix adjustment that is based on out-of-date data and implicitly violates the limits place by Congress on the size of

rebasing adjustments. As we noted in our CY16 comments, Section 3131(a) of the Affordable Care Act (ACA) required CMS to "rebase" the home health payment rate to better align payments with costs. Congress mandated that the revised payment amount should be calculated considering factors such as the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. Congress limited the amount that CMS may reduce the payment amount each year to no more than 14 percent of the 2010 payment rate phased in equally over four years between 2014 and 2017. In other words, Congress limited CMS to reducing home health payment rates to no more than 3.5 percent of the 2010 payment rate each year. CMS implemented this provision via rulemaking beginning in 2014. 2016 will be the third year of the four year rebasing implementation. The reliance on an earlier legislative authority to justify an additional type of rebasing cut above the more recent cap on rebasing cuts is clearly contrary to Congressional intent. Instead, we urge CMS to adhere to the limits on home health rate cuts established by Congress. At the conclusion of the four year rebasing period, CMS should evaluate the impact of the rebasing adjustments and consult with Congress before considering additional cuts based on intensity of services i.e. nominal case mix growth.

VNAA Comment:

CMS has again adjusted the case mix weights associated with the various Home Health Resource Groups (HHRGs) upon which the HHPPS system adjusts the actual payment made for each individual case. This is intended to reflect average utilization of services based on patient condition. The purpose of these adjustments is to better match average agency resource use to the payment made for each HHRG. These new weights shift payments to HHAs in unpredictable ways related to each individual agency's distribution of patients.

VNAA Comment:

We understand that the proposal is designed to be budget neutral but because the budget neutrality adjustment is applied across all payments, VNAA is concerned that this proposal may cause significant variation in payment depending on an individual HHA's typical case mix. We believe CMS should produce significantly more detailed impact analyses to assure that the agency specific impacts of these ongoing adjustments to individual case mix weights are not creating unfair impacts on individual agencies that are lost in the aggregate impact analyses. While we value the attempt to improve distributive payment accuracy we are concerned that the current impact analysis is so broad at to mask potential impact issues.

CMS has separately published on its website the wage index table that will be applicable to home health payments in 2017. CMS again uses the pre-floor, pre-reclassified wage index data produced for hospitals and based on hospital wage data rather than using home health data. It also persists in refusing to allow agencies to reclassify to more appropriate wage index areas even when hospitals in the same geographic location have been reclassified to higher wage index areas.

VNAA Comment:

VNAA continues to believe that using the pre floor pre reclassified hospital wage data for HH is inherently flawed particularly because CMS persists in using hospital rather than home health data and refuses to allow HHA's to reclassify to the same level as hospitals in their area. We have grown weary of the perennial excuses that CMS has made for turning a blind eye toward the clear inaccuracy and inequity in this system. CMS has responded that an accurate system would be costly for CMS to implement, that Congress would have to specifically authorize a change in the wage index used (Notwithstanding the explicit authority in the original PPS legislation delegating this authority to the Secretary), and that many agencies might not like the outcome of more accurate wage index values. Although CMS has acknowledged the problems in wage index calculation in the Hospital payment regulations it makes excuses each year for its inaction. As margins get thinner, inaccurate

wage index adjustment is undermining the payment accuracy that CMS is working to achieve via other adjustments. It is time for CMS to address this problem seriously with the acknowledgment that, while hard and controversial, it is necessary.

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

Recognizing Home Health Agency Services

VNAA is concerned that CMS's proposed payment policy for negative pressure wound therapy (NPWT) using a disposable device does not adequately recognize the home health agency's services in furnishing NPWT. Currently, home health agencies are able to bill for a visit relating to the DME NPWT device. In order for disposable NPWT devices to be treated similarly, home health agencies should be able to bill for a visit relating to disposable NPWT devices.

Interpretation of Section 504 of the Consolidated Appropriations Act of 2016

CMS proposes that in instances where the sole purpose of a home health agency visit (by a registered nurse, physical therapist or occupational therapist) is to provide NPWT using a disposable device, that Medicare will not pay for the visit under the home health prospective payment system. Rather, CMS proposes to have the furnishing of NPWT using a disposable device paid using the hospital outpatient prospective payment system (OPPS) amount, which CMS states, "includes payment for both the device and furnishing the service."[10] CMS states that "the HHA must bill these visits separately under type of bill 34x . . . along with the appropriate HCPCS code . . . Visits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x)."[11]

VNAA contends this billing approach is inconsistent with Section 504 of the Consolidated Appropriations Act of 2016 (Pub. L. 114-113) because the statute explicitly sets payment only for the disposable NPWT device, not the service related to NPWT. Section 504 amends 42 U.S.C. 1395m by adding a section on "Payment for Applicable Disposable Devices", specifically mandating that the Secretary will make payment to a home health agency for "an applicable disposable device" as defined by the statute to be a disposable NPWT device that is a substitute for the durable medical equipment item for NPWT.[12] The statute also states that the "separate payment amount established under this paragraph *for an applicable disposable device* for a year shall be equal to the amount of the payment that would be made under section 1833(t) (relating to payment for covered OPD services) for the year for the Level I Healthcare Common Procedure Coding System (HCPCS) code for which the description for a professional service includes the furnishing of such device."[13] Section 504 states and then reiterates that the statutorily mandated payment is being set for the device for disposable NPWT and that the payment rate is set at the OPPS rate captured in Level I HCPCS codes.

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

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[10] 81 Fed. Reg. 128 at 43743.
[11] *Id.*
[12] 42 U.S.C. 1395m(s)(1)-(2).
[13] 42 U.S. C. 1395(s)(3) (emphasis added).

Not only is the statute clear that this separate payment is for the disposable negative pressure wound therapy device only, the statute also specifies that the device payment is "separate from the payments otherwise made under section 1895,"[14] referring to payments under Home Health PPS. Thus, payments for the disposable NPWT device are separate from payments for services delivered by the home health agency relating to that device. The home health agency's service payments would be made under HH PPS. Furthermore, the home health agency's services relating to wound care more broadly for the beneficiary would also be separately paid. Thus, in either case, separate payment for the home health agency's services would be paid separately under HH PPS.

This interpretation of the statute is consistent with a Congressional intent to put a home health agency's incentives to have its patients use the disposable NPWT device on par with the incentives associated with the DME NPWT device.

Implications of Interpretation of Section 504

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

NPWT using a disposable device often requires a maintenance visit, but CMS's proposed payment policy suggests that a maintenance visit would not be billable as a HH PPS visit. After a NPWT disposable device is provided to the patient, often a maintenance visit is needed to collect and remove exudate. CMS states that "[v]isits performed solely for the purposes of furnishing NPWT using a disposable device are not to be reported on the HH PPS claim (type of bill 32x)."[15] If a home health nurse were to make a needed maintenance visit relating only to the disposable NPWT device, CMS's proposed policy of not permitting home health visits relating to the disposable NPWT device to be reported on a HH PPS claim would prohibit any recognition of such a visit using type of bill 32x. If CMS is paying for the HCPCS code, which includes both the NPWT disposable device and the related services, then the home health agency would not be able to use bill 34x for the maintenance visit because this code would already have been billed on an initial visit. To bill a maintenance visit using 34x would effectively pay the home health agency twice for the same disposable NPWT device.

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

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

By allowing visits solely related to furnishing NPWT using a disposable device to be HH PPS visits billable using 32x, CMS will put the services related to furnishing NPWT on equal footing regardless of device, and avoid creating an incentive to use the DME version of the device instead of the disposable one. Currently, home health agencies that serve patients using NPWT using a DME device are able to bill for those visits using type of bill 32x as they are HH PPS visits. By allowing the service of furnishing NPWT using a disposable device to be a visit under the HH PPS, billable using 32x, CMS would appropriately allow for these visits to be counted as any other HH PPS visit. In doing so, CMS will avoid potential

[14] 42 U.S.C. 1395m(s)(1).
[15] 81 Fed. Reg. at 43743.

unintended consequences caused by different incentives relating to NPWT using a disposable device versus a DME device. In other words, if disposable NPWT-related home health visits cannot be billed under HH PPS, there may be an incentive to use the more costly, DME-version of NPWT.

VNAA Comment:

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

Definition of "Applicable Disposable Device"

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

"'(A) a disposable negative pressure wound therapy device that is an integrated system comprised of a *non-manual* vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy; (B) a substitute for, and used in lieu of, a negative pressure wound therapy durable medical equipment item that is an integrated system of a negative pressure vacuum pump, a separate exudate collection canister, and dressings that would otherwise be covered for individuals for such wound therapy.'"[16]

VNAA Comment:

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

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

Outlier Payments and Units-per-Episode

CMS proposes to use "units of time" rather than "whole visit imputed costs by discipline" in its methodology of cost outlier payments.

VNAA Comment:

VNAA recognizes and appreciates that CMS acknowledges the long-standing concern that there are disproportionate access issues for higher-cost and/or more complex patients. CMS' recognition of this pattern of barriers to care is a first step to addressing the underpayment for these complex patients that result in access issues. VNAA understands that this proposal is designed to address this problem and to redistribute payment more appropriately to higher cost patients. It is important to note that as more patients chose to use patient-centered home health services as an alternative to costly and impersonal facility-based care, the mix of complex

[16] 42 U.S.C. 1395m(s)(2) (emphasis added).

and vulnerable patients will increase. This is a desirable outcome and home health agencies are able to support these patients. However, it means that the agencies that take high levels of high risk and complex patients may continuously bump up against the outlier caps. Being overly prescriptive about the outlier cap will discourage home health agencies from taking these cases; CMS must minimize this unintended consequence.

We understand CMS' desire to curb outlier abuse and support efforts to reduce fraud and waste. VNAA has long supported CMS' efforts to use the individual outlier cap to reduce the unjustified growth in outlier payments in the past. However, the individual agency outlier cap was supported by VNAA and others as a device to curb outlier abuse, not as a way to constrain legitimate payments for medically complex patients. VNAA is concerned that the proposed adjustment based on hours of care could potentially limit home health providers in small and / or rural areas who provider short but necessary visits but travel a great deal of time to serve that patient.

Specifically, VNAA seeks more information about the implications of the proposed cap on units of care. The proposed cap on units is consistent with longstanding CMS definition of statutory limit on part time and intermittent services—but it does not allow for flexibility in the definition of that limit for those true outlier patients who have medical need for extremely high units of care. At a time when there are a growing numbers of more frail, high need patients being discharged directly home after a hospitalization, it is vital that the number of hours that a patient need be determined by those treating the patient. This work can be done within the confines of "part time and intermittent services", but the exact structure of time should be left to the providers with an eye to the total cap limitation. It is our belief that the 32 unit / eight hour a day definition of the proposed cap may inadvertently cause patients to discharge to or remain in skilled nursing facilities and needlessly increase overall healthcare expenditures. CMS should provide greater flexibility in this area bearing in mind its experience under the Interim Payment System when high needs patients could not be accommodated under IPS and the human impact and political fallout was embarrassing for both the home health community and CMS.

Home Health Quality Reporting Program (HH QRP) Update

CMS proposes to adopt for CY 2018 four measures of payment determination to meet the requirements of the IMPACT Act: All-condition risk-adjusted potentially preventable hospital readmission rates; Total estimated Medicare spending per beneficiary; Discharge to the community; and Medication reconciliation.

VNAA Comment:

VNAA conditionally supports the addition of these measures. We have worked with CMS on the implementation of the IMPACT act and have shared our concerns about the timeline and appropriateness of various measures.

With regards to the preventable hospital readmissions measures, VNAA seeks clarification about how observational status stays or emergency department visits will be included in the measurement. It is important that CMS clearly state if—and how—these visits, and their related costs, will be included in readmissions data.

Medication reconciliation and adherence measures are of concern in the home health setting. VNAA believes that as designed the measures do nothing to improve patient safety and have little value on process beyond checking a box. The discussion about medication reconciliation process measure raises many questions and will be difficult to uniformly calibrate.

For example, clinicians will be measured on whether they were "responsive to potential or actual clinically significant medication issues, when such issues were identified"—but there are many unanswered questions behind this language.

- When and how are medication issues identified?
- Does this mean that after a patient is hospitalized, and the root cause might have been a medication issue, that then the home care chart is examined for evidence the clinician tried to head off the problem?
- Does this mean that the clinician sees a potential risk from two much aspirin hidden in multiple compound products?
- Who has ultimate responsibility for medication reconciliation and patient compliance?

What's more, many underlying medication problems that result in damage are never identified or tagged as the result of failure to reconcile medication. These problems will be underreported with these process measures. Home health providers will be held accountable to this as a quality measure but these underlying process questions identify the many, porous assumptions that will make it difficult to establish a firm standard for compliance. This is a process measure but with no set scale or assurance that all 90 percent compliance scores are equal.

VNAA encourages CMS to think critically about the appropriateness of measures on medication reconciliation in home-based settings. Whereas other post-acute care settings have near total control of medication usage, the home is a very different environment in which home health providers have limited control over medications. Medication reconciliation in home-based care settings will require different supports and measures to ensure patient safety and will need to be evaluated differently than facility-based care.

There are additional considerations for future IMPACT Act measure development in the home health setting. Stemming from the fact that home health services are significantly different than other post-acute settings. Future measures must account for these differences. Of note, home health agencies will have unique challenges with process measures related to falls in people over 65 in home-based settings. Home health agencies respect patient choice and patient-centered care; they do not have the ability to control everything about a patient's home or the ability to minimize certain fall risk factors in the home. This is different than in other post-acute settings where the facility is in control and can modify the environment to minimize risk. While VNAA shares the important goal of minimizing patient falls, it is important to recognize the challenges in home settings—and not to compare process and outcomes to facility-based providers.

VNAA strongly rejects the development of measures that assess the change in function as compared to the expected function of a patient. First, this implies that there is an expectation of improvement in home health patients and hinges on how "expected function" is defined and determined. It is not an automatic failure of care if function does not improve. More importantly, this measure directly contradicts the intent of the *Jimmo v. Sebelius* settlement which guarantees access to home health benefit to patients who have no reasonable expectation of improvement—but to maintain function and reduce deterioration.

Additionally, VNAA strongly supports the work of the National Quality Forum to assess socio-demographic and economic factors and the appropriateness of including them in risk adjustment calculations. As such, we do think that applying the philosophy described by CMS when proposing to exempt measures "causing concern for public safety" from the standard rulemaking cycle is necessary. If data available prior to the completion of the planned process which demonstrates a clear risk to patients, from any perspective (e.g., access to care, duration of care, start of care) due to the lack of risk adjustment related to socio-demographic concerns, adoption of the adjustments should occur immediately. Continuous monitoring and analysis of the impact of these measures is critical.

The Home Health Conditions of Participations (CoPs) require HHAs to submit OASIS assessments as a condition of payment and for quality measurement purpose. HHAs that do not submit quality measure data are subject to a two

percent reduction in their annual payment update (APU). This will be incrementally increased over a three-year period beginning in 2017.

VNAA Comment:

The requirement that HHAs submit both admission and discharge OASIS assessments for 90 percent of all patients will be phased in beginning 2017. CMS must monitor this implementation and report data to ensure the smooth implementation of this process. They must provide appropriate notice for agencies that are falling short so that remedies can be taken.

VNAA also calls on CMS to quickly and urgently publish revised CoP as soon as possible. These revised CoPs, which are currently pending, will provide guidance, stability and a clear path forward. This is appropriate and more desirable than annual incremental changes. Revised CoPs will allow agencies to plan, make necessary adjustments and ensure the robust participation of high-quality agencies.

CMS has identified 28 HH measures that were either "topped out" or determined to be of limited clinical and quality improvement value. These measures will no longer be included in the HHQI.

VNAA Comment:

VNAA appreciates that CMS continues to refine the home health measures and data set. The removal of topped out measures is critical for continued quality improvement.

Home Health Value Based Purchasing Demo

CMS proposes to eliminate Smaller- and Larger-Volume Cohorts solely for the purposes of setting Performance Benchmarks and Thresholds

VNAA Comment:

VNAA members, particularly small agencies, have expressed strong concern about how achievement thresholds would be calculated for the cohort sizes, with a particular worry about any differences between small and large cohort sizes. If there is too much variability, or the sample size is too small, the smaller-volume agencies may be held to performance standards that are greater than the large-volume HHAs would be required to achieve creating an inequitable and different standard based solely on volume.

VNAA supports CMS' proposal to calculate the benchmarks and achievement thresholds at the STATE level only (and not with the cohorts) beginning with CY2016. However, we encourage CMS to annually monitor and report the differential impact of unified state-level benchmarks and achievement thresholds by the smaller- and larger-volume cohorts to ensure that this policy does not produce unintended consequences.

The CY2016 HHPPS required that where there are too few HHAs in the smaller-volume cohort in each state to compete in a fair manner, those agencies would be included in the larger-volume cohort for the purposes of payment adjustment.

VNAA Comment:

VNAA appreciates that CMS recognized VNAA's strong concern about the small number of small-volume agencies in some states and how that might result in an unleveled competition between agencies. We remain vigilant in understanding how having a small-volume cohort will impact these agencies and urge CMS to consider the necessity of two cohorts.

In general, we support the proposal that if a state has a smaller-volume cohort of less than 8, those HHAs will be included in the larger-volume cohort for the purposes of calculating the LEF and payment adjustment percentages. We request that CMS continually monitor the impact of this proposal on agencies and provide annual updates on how small agencies perform. Specifically, we request a comparison of how smaller-volume cohorts in all states would compare if included in the larger-volume cohort.

CMS proposes to remove four measures from the measure set beginning with the CY 2016 PY calculations: Care Management: Types and Sources of Assistance; Prior Functioning ADL/IADL; Influenza Vaccine Data Collection Period and Reason Pneumococcal Vaccine Not Received. The quality measures will no longer be known as the "starter set."

VNAA Comment:

VNAA has continuously requested that CMS trim the number of reporting measures in the HHVBP program in order to simplify administration and reporting. This will reduce the reporting burden on HHAs and allow them to focus on quality improvement efforts. We have also previously expressed comments on specific new measures, including the four CMS proposes to eliminate in CY17. We support the removal of these measures and encourage CMS to continue to streamline the quality measures.

VNAA has no issue with eliminating the phrase "starter set" from the quality measures set. However, we seek assurance that the measures will continually be revised and reexamined. While this may no longer be a starter set, CMS should not imply that it is a static set of measures.

CMS proposes to require annual rather than quarterly reporting on of the new measures: Influenza Vaccination Coverage for Home Health Personnel," with the first submission in April 2017.

VNAA Comment:

VNAA supports the proposed change will simplify the reporting requirements and align it with the annual nature of influenza.

CMS proposes to increase the timeframe for submitting New Measure data from 7 to 15 calendar days to account for weekends and holidays.

VNAA Comment:

VNAA supports this proposal but encourages CMS to look for additional simplifications and timelines to ease the reporting requirements. HHAs should be offered as much administrative support and simplicity as possible in order to make reporting seamless. VNAA members have expressed significant concern about the ridged timelines and short reporting periods across the HHVBP demonstration. This proposal makes a limited nod to simplifying reporting by adding additional time for reporting.

CMS proposes an appeals process that includes a period to review and request recalculation of both the Interim Performance Report and the Annual Total Performance Score (TPS) and Payment Adjustment Reports. The proposal included specific timeframes for the submission of recalculation requests.

VNAA Comment:

A robust and transparent appeals process is critical in all administrative processes. Additional layer of appeals strengthens the process and allows HHAs to challenge CMS decisions that are incorrect, arbitrary or capricious.

VNAA supports the addition of a second layer of appeal to contest the results of the CMS Recalculation. It is a reasonable step to allow HHAs to submit a reconsideration request for Annual TPS and Payment Adjustments. VNAA encourages CMS to enforce firm timelines by which HHAs will be notified of the decision of their appeal and for CMS to appropriately staff the appeals team to meet these targets.

VNAA cautiously supports that final TPS and payment adjustment reports will be sent to the HHAs in a final form no later than 30 calendar days before the payment adjustments would take place to allow extra time for the appeals process to take place. While VNAA supports more time for HHAs to receive their payment adjustment reports so that they can operationalize the payment adjustments, VNAA understands that this balances additional time for the appeals. We stress, however, that with this additional time VNAA expects the timely and transparent adjudication of appeals and notification to HHAs.

CMS will publically display the HHA total performance scores in the future and are considering various public reporting platforms including Home Health Compare and the CMMI webpage as a vehicle for maintaining information in a centralized place.

VNAA Comment:

VNAA does not oppose the public display of TPS on Home Health Compare or on the CMMI website so long as certain conditions are met. First, a clear and transparent process must be developed in partnership with stakeholders to identify what will be posted. Secondly, HHAs must have the opportunity to view their scores and have full access to the appeals process in advance. Thirdly, it is critically important that the language on the HH Compare website be clear about what the TPS scores represent (and what they do not) so that the average consumer fully understands the implications of the data listed on the site and can make reasonable and well informed decision using these data.

Finally, VNAA contends it is also of paramount importance that attention be paid to how consumers access the information on Home Health Compare with a particular emphasis on health and health insurance literacy. As this project evolves and becomes more public-facing, the information presented must be accessible at a low-literacy level and clearly presented for patients and caregivers. In addition, public information should meet standards for cultural and linguistic competency.

VNAA appreciate the opportunity to comment on the 2017 Home Health Prospective Payment System proposed rule. Please contact Joy Cameron, Vice President of Policy and Innovation at jcameron@vnaa.org or 571-527-7536 with any questions or concerns.

Regards,

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