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SEP 25

WE PUT THE CARE IN HOME HEALTH CARE
VINEYARD NURSING ASSOCIATION, INC.
HEALTH & HOME CARE SERVICES

Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments on proposed 2007 rule.
CMS-1304-P
Section II. Provisions of the Proposed Regulations
Section F. Hospital Wage Index

Dear Sirs:
The Vineyard Nursing Association on Martha's Vineyard appreciates the opportunity to submit the following comments on the proposed rule for the FY2007 Home Health Prospective System Rate Update.

Proposed Rule for 2007

In 2005 the only PPS hospital data for rural Massachusetts was from Franklin Medical Center in Franklin County, MA. In 2006 Franklin Medical Center became attached to Springfield, MA and consequently there was no PPS hospital data available in any rural county in Massachusetts. CMS chose at that time to use the SWI for rural Massachusetts from the previous year(2005) to set the SWI that would be used in Dukes and Nantucket counties for 2006.

The proposed rule for 2007 suggests CMS use the same SWI again in 2007.

We disagree with this approach. Last year at this time we commented that using the SWI from 2005 to set 2006 was not reasonable because CMS acknowledges that the rule is not based on any current data and, in the main, it did not accurately reflect the costs and salary and wage information for Dukes and Nantucket counties in Massachusetts.

We again do not believe that leaving the salary wage index the same achieves the goal that you desire because, minimally, this approach violates your own guidelines which states that "any methodology to impute a rural wage index would be able to update wage

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Located at the Martha's Vineyard Hospital

data from year to year." The current approach violates this guideline because in no way does this approach attempt to update wage data annually.

We also disagree for the same reason we disagreed last year. This approach does not accurately reflect the costs and salary and wage information for Dukes and Nantucket counties resulting in placing undue financial burdens on the three agencies in Massachusetts affected by the ruling.

Critical Access Hospital Data

We believe that, above all, the SWI should reflect local data from the counties that the SWI is supposed to represent. In the case of Dukes and Nantucket, data is available from Martha's Vineyard Community Hospital and Nantucket Hospital. We recognize that these hospitals are currently designated Critical Access Hospitals.

However, this does not mean that their data is not accurate nor accessible. We strongly believe that one of the guiding principles in establishing SWI's should be that all data should be local and that this principle should be considered critical to establishing accurate and valid SWI's.

We recognize that as Critical Access Hospitals, MV Community and Nantucket Cottage Hospitals are not required to submit data to your group within CMSA. That does not mean that these hospitals do not submit data to CMS. In fact, they submit cost data annually and they currently submit "Occupational mix survey" data quarterly which is the data that was regularly submitted when the two hospitals were PPS hospitals.

Currently CMS ignores this data because, at this time, only the cost data is relevant. However, this could be modified by CMS so that a new rule could be:

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Using a Proxy-alternate #1

CMS makes a suggestion that the four New England states' SWI's be averaged together to impute an SWI for Massachusetts. We strongly disagree with this approach. While it is simple enough to average the four states SWI's, all that is accomplished is you get an average. The mathematics works but have you really imputed a rural SWI that has any relevance to the problem you are trying to solve. Have you created a proxy that "approximates" the economic conditions for the area that has no direct data. Clearly not in this case.

We maintain that the premise that across any wide region the economics are similar is severely flawed. I submit the attached chart "A" which shows the SWI's across New England and also shows the county and state median value for homes and median and family incomes. We believe that the numbers clearly demonstrate that the best proxy for Dukes and Nantucket is Barnstable county. I say this knowing that you have indicated that, "any methodology to impute a rural wage index should use rural wage data to derive the rural wage index value".

We disagree with this guiding principle on the grounds that the circumstances are so different in this situation as to make the above statement irrelevant. It seems to us that in our situation and any similar situation across the U.S. you are saying that step one in selecting a proxy for a rural region without data is to go outside the boundary of the State that is affected by the situation in order to find comparable data. In effect you are suggesting that CMS reimbursement for one state should be based on conditions in another state or group of states. We believe that this is contrary to the entire effort CMS makes across the U.S. to provide an SWI based on local data and why would you do that when comparable data is available within the affected state irrespective of the formal classification as metropolitan or non-metropolitan. We can't believe that any state would want their Medicare reimbursements to be based on data from another state. That guiding principle might have been relevant when you were working within a state as in the situation when Dukes and Nantucket counties had no data but Franklin county did have data, However, the current situation demonstrates the fallacy of applying this principle to this case.

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We would further argue that health data exists to support our argument that Barnstable county is the best suited as a proxy for Dukes and Nantucket. Specifically, in addition to the data on Chart A showing a correlation between the median housing costs and the SWI's in Barnstable, in 2003 the wage data for the hospitals in Barnstable, Dukes, and Nantucket were as follows:

	2003 average hourly wage data
Barnstable County, MA	
Falmouth Hospital	$29.68
Cape Cod Hospital	$31.10
Dukes County, MA	
Martha's Vineyard Community Hospital	$29.61
Nantucket County, MA	
Nantucket Cottage Hospital	$31.13

Please remember that in 2003, these hospitals were all "PPS" hospitals.

While Chart "A" shows a correlation between median housing prices, the above data shows a strong correlation for the health data for hospitals on the Cape & Islands(Barnstable, Dukes, and Nantucket counties) and should be used to establish Barnstable as our proxy now and for the future.

Lastly, we do not select Barnstable randomly from the many counties in Massachusetts. Barnstable county is the county that geographically abuts Dukes and Nantucket albeit separated by Vineyard Sound. Furthermore, the "Cape and the Islands" are generally considered one region of Massachusetts and have been coupled often, especially when applying for federal grants such as the the Health and Human Services HRSA Community Action Program grant(CAP) or the HRSA Integrated Service Delivery Initiative grant(ISDI). You need only look at the Massachusetts special license plates which also refer to the "Cape and the Islands".

The point is that, irrespective of the formal non-metropolitan designation, economically, geographically, and statistically Dukes and Nantucket are married to Cape Cod which is also known as Barnstable county.

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In summary, we believe that Barnstable County should be the proxy for Dukes and Nantucket because:

A. The health data for Dukes and Nantucket strongly correlate to the health data for Barnstable.
B. There is a high correlation between median house prices and SWI and Barnstable comes closest to Dukes and Nantucket
C. CMS should want to use local data rather than provide Medicare reimbursement for one state based on economic data from another.
D. Barnstable County abuts Dukes and Nantucket geographically, separated by only 3 or so miles of the Vineyard Sound.
E. Barnstable and Dukes and Nantucket are considered one region by Massachusetts.
F. Barnstable and Dukes and Nantucket have teamed together on federal grants because of the similarity of the economics and demographics further demonstrating the similarity between the counties.
G. The Data is updatable. Once Barnstable is established as the proxy, the data CMS requires is updated annually and meets all of the guiding principle save the one we think is not relevant to the situation. We understand further that the guiding principles are examples of past practices and not statutory in nature.

We suggest that the general rule be:

For any rural county or counties where no PPS data exists the nearest county geographically within the state that can be shown by the affected counties to be similar economically should be used as the proxy for the county or counties without data.

Using a proxy- alternate #2

We know we have made a strong case for using Barnstable County's SWI as a proxy for Dukes and Nantucket. Further, we believe that we have made a compelling argument that non-rural data could and should be used, especially when it mirrors the rural area(where no data exists) so closely and helps to avoid seeking proxy data from another state.

However, if you examine the data in Chart "A", we believe that if CMS decides that the data must be rural, then the only solution that makes sense to us is to use the rural SWI in Connecticut as a proxy for Dukes and Nantucket Counties.

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The data on Chart "A" shows a strong correlation between Massachusetts and Connecticut economically.

A. Massachusetts has the highest housing costs by 11% with Connecticut 2nd more than 25% higher than the next state.
B. Connecticut has the highest per capita money income by 10.8%, but Massachusetts is 2nd.
C. Connecticut has the highest median household income by 7%, but Massachusetts is 2nd .

Since we have showed that our first proxy choice is Barnstable County, it is interesting to note that only in Fairfield County, Connecticut does the housing costs begin to approach the costs in Dukes and Nantucket.

Fairfield County is a metropolitan county with an SWI of 1.2681 which is less than 1/10th of 1% more than the SWI for Barnstable County.

However, the only rural county in New England whose housing costs comes close to the Massachusetts State average housing cost, let alone the housing costs in Dukes and Nantucket County, is Wyndham County, Connecticut.

Wyndham has housing costs of $178,800 compared to $185,700 for the Massachusetts State average or $304,000 for the Dukes County average.

While housing and income data is not "health data", the 2003 "health data', shown again here

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Martha's Vineyard Community Hospital	$29.61
Nantucket County, MA	
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demonstrates the linkage to Barnstable County which has virtually the same SWI as Fairfield County.

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The point here is that, as stated early, a mathematical averaging of the New England States' SWI's does not provide a solution to the problem. The diversity of the economics within the New England region argues for seeking a specific state that best approximates the state in question and, where possible, the county seeking a proxy. If CMS insists on providing a rural proxy from another state within the New England region, **then the SWI for Wyndham County, Connecticut is the only choice.**

We look forward to your response to these comments and the final rule.

Regards,

Robert Tonti
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VNAA Visiting Nurse Associations of America®

SEP 25 2006

the voice of home healthcare

September 20, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

I am writing on behalf of the Visiting Nurse Associations of America (VNAA) to comment on the proposed rule: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007, CMS-1304P. The VNAA represents over 400 non-profit, community-based home health agencies across the United States. We appreciate the opportunity to provide comments on this proposed rule.

Comments under Provisions of Proposed Regulation

We do not believe that the **proposed market basket update** adequately addresses the problems home health agencies are experiencing due to the rapid increases in the cost of gasoline over the last two years. Because the home health agency benefit is built on the premise moving clinical staff from home-to-home in their communities, the increased cost of gasoline has been taking a heavy financial toll on our members as they try to find the resources to adequately cover transportation costs. In a letter VNAA received from Herb Kuhn responding to a plea we made last year to Administrator McClellan on this issue, he indicated that we could look for relief on our gasoline cost problems to the 2006 home health market basket index. As you are aware, Congress eliminated that update. Moreover the data informing the home health market basket calculation has not kept pace with these sudden price spikes. We would urge CMS to re-examine the update methodology for 2007 to assure that the most up-to-date cost report and economic data is used to assure that the increased cost of gasoline being experienced by home health agencies is fully reflected in the 2007 update.

On the issue of the **DRA quality reporting requirement**, we agree with the proposal to use the submission of OASIS quality data on publicly reported measures as meeting the DRA requirement for submission of quality data. We also endorse the use of the existing OASIS data submission platform for the collection of any subsequent quality reporting requirements. It clearly is the most efficient way to manage the current and future reporting and collection requirements.

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Silver Spring, MD 20910
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We would urge, of course, that ample lead time be allowed for any changes in OASIS reporting requirements to allow for both software changes and staff training. This has not always been the case in the past and has proven very disruptive and costly to remedy. We would urge that CMS involve VNAA and other home health associations, in discussions of possible additions to reported quality measures prior to formal regulatory actions. This would serve to prepare the home health community well in advance of possible changes and allow for an exchange of ideas before the formal rulemaking process begins.

We also share CMS's interest **in improving and refining the current quality measurement system** for home health. Improvement and refinement is absolutely necessary before there is any move to use such measures in a pay-for-performance system. While the existing measures have proved useful as a guide to agency self-improvement and even as a rough guide to comparisons in quality, the current system remains far short of the kind of quality measurement system that would allow fair payment differentials.

There have been numerous suggested refinements to the OASIS data collection instrument that have been made by the home health community, including VNAA and its individual members, over many years. Most have yet to be incorporated into the instrument. These generally relate to the inadequacy of the form in capturing significant improvements in patient status because they do not fall within the "forced-choice" response currently in the instrument. These include: the progression from walker to cane and endurance in ambulation, the progression to sink washing under bathing, the insensitivity of the 50% rule in determining progressions in the ADL area generally, and the incomplete classification of the severity of wounds and wound types.

We would also note that hundreds of pages of clarifying instructions and Q and A's have not led to increased consistency in the completion of OASIS. OASIS questions and responses need to be recast in ways that allow clinicians to feel confident that they can produce valid and reliable OASIS responses based on their core clinical competencies, without recourse to hundreds of pages of clarifying instructions. We suggest that questions that have required the most "clarification" are probably more in need of restatement and refinement than additional pager of external explanation.

We also believe that there is ample evidence that the current OBQI risk adjustment methodology is not sufficiently reducing variation in outcome scores based on factors unrelated to patient care. Clearly other variables are systematically driving outcome scores such as the volume of Medicare-Medicaid dual-eligibles, average length of stay, physician practice patterns and penetration of managed care programs. Until there the home health community is convinced that outcome scores are sufficiently risk adjusted, it will be difficult to reach a consensus on pay for performance.

Thus OASIS and OBQI refinement is an important first step in performance-based payment. That having been said, we believe some OASIS measures stand out as those most closely related to agency quality performance, subject to the qualifications noted in parenthesis. These include: improvement in pain (needs better risk adjustment), improvement in oral medication management (needs adjustment for caregiver assistance), improvement in ambulation (needs refinement to allow more gradations of improvement), discharge to community (needs adjustment for hospice discharge) and hospitalization (needs better risk adjustment). Each of these has shortcomings (noted in parenthesis) that should be addressed but they clearly stand out from among other measures within the home health community.

We also believe that process measures need to be added to outcome measures to provide a more balanced approach to quality measurement. While researchers have not focused their attention on validating process measures specifically in home health, we believe there is a consensus in the home health community that certain process measures stand out for consideration in quality measurement. These include: use of a CHF protocol, timely admission following referral, fall prevention protocols, diabetic protocols, resolving patient concerns after hours, COPD protocols and timely return of patient calls. We also believe that patient satisfaction measures should be employed but carefully refined to assure focus on clinically relevant issues rather than issues of popularity...our best clinicians are those who focus achieving positive results in patients' lives. Finally, it is our impression that agencies that provide the full range of Medicare home health services are better equipped to meet patient needs than those that offer only the minimum required for Medicare certification. This structural characteristic should be considered among quality measures.

Should Congress mandate performance-based measures, VNAA and its members are eager to work with CMS in the refinement of OASIS and the development of quality measures suitable for "pay for performance."

On the issue of **Outlier PPS payments**, we agree that CMS has an obligation to modify PPS outlier criteria each year until the 5% set-aside is realized. We would urge CMS to assure that data is available before the final rule to allow any needed adjustments.

On the issue of **wage index conversion to CBSA and fairness**, we believe that the shifts in wage index values that have occurred over the past two years due solely to redesignation from MSA to CBSA areas highlight the problems inherent in the current wage index methodology. Specifically the boundaries created around wage index areas do not appropriately capture the wage-related cost of all agencies in the area any more than they capture that of all hospitals in these same areas. With over 20% of hospitals now reclassified to more appropriate areas, denying home health agencies the same rights hospitals enjoy to seek reclassification is both unfair and inequitable. It is unfair because CMS has the broad statutory authority to determine the wage index applicable under the PPS system and could incorporate a reclassification provision similar to that enjoyed by hospitals through rule-making. The current system is inequitable because home health agencies must compete in the same labor markets as reclassified hospitals and cannot

match hospital salaries supported by Medicare payments to reclassified hospitals. At a minimum, agencies serving the same county as a reclassified hospital should be given wage index parity for services it provides within that county. CMS has the explicit statutory authority to establish the wage index adjustment methodology under PPS and needs to begin using that authority to determine a fairer and equitable wage index applicable to home health agencies. In a related issue, we appreciate CMS using its broad wage index authority to provide a transition year to cushion large wage index shifts from MSA to CBSA areas. However, each year there a lesser number of large wage index shifts driven by data errors or omissions by hospitals or by unanticipated shifts in relative wages. We also believe that the same authority CMS used to allow a transition period from MSA to CBSA areas should be applied each year to "smooth" such large and unexpected wage index reductions by phasing in such reductions over a two year period just as CMS has done under CBSA conversion.

Regarding the **rural Massachusetts wage index** issue, it is clearly inequitable to either freeze the index in time based on when PPS hospital data were last available in rural Massachusetts or to create a blended rate from among rural hospitals rates in the various States in the region when such States clearly differ significantly from each other. A simple comparison of urban wage indexes illustrates that these wages differ widely among states in the region. We believe the best approach to this problem and perhaps the only one that fully meets the criteria CMS has set out in its proposed rule, is to create a state-specific rural wage index based on data from the remaining critical access hospitals in the area. Lacking that data, CMS must be prepared to be more flexible in adopting a solution. The most efficient and equitable alternative solution would be to link each non-CBSA county to the closest CBSA county geographically and economically. In the case of Dukes County, that would be Barnstable County. In addition to geographic proximity, these counties are similar in health data, median housing prices, economic and demographic conditions. In fact these counties, together with Nantucket County, are considered one region by the State of Massachusetts. There is a strong Federal precedent to respect the boundaries of States and to defer to a State's own judgment on its political subdivisions when making Federal financial determinations. We would urge CMS to adopt this alternative rather than looking outside of Massachusetts for data influencing the citizens within Massachusetts. Only if CMS finds it necessary to temporarily assign a rural wage index to rural Massachusetts until State specific solution is implemented, would we suggest that CMS use the rural index of the closest adjoining state, in this case Connecticut. This temporary expedient would create some measure of equity while CMS implements either of the preferred solutions above.

Thank you for the opportunity to comment on this important rule. We look forward to your favorable consideration of the suggestions we have made and look forward to reviewing CMS's specific responses to these comments in the final rule. If you have any questions regarding these comments please feel free to contact Bob Wardwell in our Washington office at 240-485-1855.

SEP 25 2006

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MARTHA'S VINEYARD COMMUNITY SERVICES
111 EDGARTOWN ROAD · VINEYARD HAVEN, MA 02568

September 19, 2006

Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments on proposed 2007 rule.
CMS-1304-P
Section II. Provisions of the Proposed Regulations
Subsection F. Hospital Wage Index—Revised OMB

Dear Sirs:

The Visiting Nurse Service of Martha's Vineyard Community Services appreciates the opportunity to submit the following comments on the proposed rule for the FY2007 Home Health Prospective System Rate Update.

Proposed Rule for 2007
The Visiting Nurse Service is one of only three agencies in Massachusetts that has been negatively impacted by the rule which established the Salary Wage Index(SWI) in 2005 and in 2006.

We have worked with the Vineyard Nursing Association(VNA) in responding to the proposed rule for 2007. We concur with the VNA's comments that either keeping the same SWI in 2007 or imputing the SWI by averaging the New England States' SWI's together is not an acceptable approach in establishing the SWI for rural Massachusetts in 2007.

The 2007 rule proposes that the new SWI be the same as in 2006 and makes no attempt to update the data because no PPS hospitals exist in the rural counties affected. We believe that a better methodology exists in the situation where no current data exists.

We also agree that averaging the SWI's of the New England states together does not achieve an accurate or valid SWI for rural Massachusetts. We think that having local data included in the calculation is the optimum goal in creating an SWI and we think there are two ways to achieve this.

Option 1-Data from Critical Access Hospitals
We understand that in the past CMS allowed Critical Access Hospital data to be part of the data base which establishes the SWI. Since Dukes and Nantucket counties each have a CAH in their county, we suggest that this data be allowed into the data base and form the basis for the SWI for these two counties. Further, we would suggest that on a national basis that this methodology be used anytime no PPS data exists.

Option 2- Use Barnstable, MA county's SWI as a proxy for Dukes and Nantucket County.
We strongly agree with the VNA and believe that their comments on this subject establish the linkage between Dukes, Nantucket, and Barnstable county to justify using Barnstable as a proxy. We believe that, above all else, the guiding principle should be to seek local data irrespective of the type-metropolitan or non-metropolitan. We also recognize that Barnstable, Dukes, and Nantucket which are also known as the "Cape and the Islands" are already established as a region within the state of Massachusetts and for federal purposes in seeking HHS grants.

This solution meets all the guiding principles save one and we believe that the intent of CMS should be to use local data because it will clearly be more accurate than out of state data as long as it can be shown to accurately reflect the counties with no current data. And we believe we and the VNA have presented strong evidence to justify implementing this methodology in seeking a proxy.

Option 3- An alternate proxy methodology. Use rural Connecticut as a proxy for Dukes and Nantucket counties.
Once again we concur with the VNA and support their position that the economic conditions within Massachusetts most approximates Connecticut and that the housing prices correlate strongly with the SWI in the two states. We agree that because Connecticut mirrors Massachusetts that the only SWI in New England that approaches an accurate and valid reflection of the Salaries and Wages in Dukes and Nantucket is the SWI for rural Connecticut.

We hesitate to suggest this solution because it does not use local data, however, if CMS insists on using out of state data, then the rural Connecticut data is the only choice. This solution does have the benefit of being updated annually and meets your other criteria.

Summary
Because we have referenced the VNA comments to the proposed 2007 rule, we have attached a copy of their letter.

We look forward to your response to these comments and the final rule.

Regards,

Julia Burgess
Executive Director

Cc: Robert Tonti, Vineyard Nursing Association

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We again do not believe that leaving the salary wage index the same achieves the goal that you desire because, minimally, this approach violates your own guidelines which states that "any methodology to impute a rural wage index would be able to update wage data from year to year." The current approach violates this guideline because in no way does this approach attempt to update wage data annually.

We also disagree for the same reason we disagreed last year. This approach does not accurately reflect the costs and salary and wage information for Dukes and Nantucket counties resulting in placing undue financial burdens on the three agencies in Massachusetts affected by the ruling.

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We believe that, above all, the SWI should reflect local data from the counties that the SWI is supposed to represent. In the case of Dukes and Nantucket, data is available from Martha's Vineyard Community Hospital and Nantucket Hospital. We recognize that these hospitals are currently designated Critical Access Hospitals.

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This would solve the problem. The data is available. The Hospitals are willing to provide them as part of a requirement whenever the "no local data" condition exists. The CAH data could then be used to establish accurate SWI's for Massachusetts or any other state in the same situation.

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We maintain that the premise that across any wide region the economics are similar is severely flawed. I submit the attached chart "A" which shows the SWI's across New England and also shows the county and state median value for homes and median and family incomes. We believe that the numbers clearly demonstrate that the best proxy for Dukes and Nantucket is Barnstable county. I say this knowing that you have indicated that, "any methodology to impute a rural wage index should use rural wage data to derive the rural wage index value".

We disagree with this guiding principle on the grounds that the circumstances are so different in this situation as to make the above statement irrelevant. It seems to us that in our situation and any similar situation across the U.S. you are saying that step one in selecting a proxy for a rural region without data is to go outside the boundary of the State that is affected by the situation in order to find comparable data. In effect you are suggesting that CMS reimbursement for one state should be based on conditions in another state or group of states. We believe that this is contrary to the entire effort CMS makes across the U.S. to provide an SWI based on local data and why would you do that when comparable data is available within the affected state irrespective of the formal classification as metropolitan or non-metropolitan. We can't believe that any state would want their Medicare reimbursements to be based on data from another state. That guiding principle might have been relevant when you were working within a state as in the situation when Dukes and Nantucket county had no data but Franklin county did have data, but this situation demonstrates the fallacy of applying this principle to the current circumstances.

We would further argue that health data exists to support our argument that Barnstable county is the best suited as a proxy for Dukes and Nantucket. Specifically, in addition to the data on Chart A showing a correlation between the median housing costs and the SWI's in Barnstable, in 2003 the wage data for the hospitals in Barnstable, Dukes, and Nantucket were as follows:

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While Chart "A" shows a correlation between median housing prices, the above data shows a strong correlation for the health data for hospitals on the Cape & Islands(Barnstable, Dukes, and Nantucket counties) and should be used to establish Barnstable as our proxy now and for the future.

Lastly, we do not select Barnstable randomly from the many counties in Massachusetts. Barnstable county is the county that geographically abuts Dukes and Nantucket albeit separated by Vineyard Sound. Furthermore, the "Cape and the Islands" are generally considered one region of Massachusetts and have been coupled often, especially when applying for federal grants such as the the Health and Human Services HRSA Community Action Program grant(CAP) or the HRSA Integrated Service Delivery Initiative grant(ISDI). You need only look at the Massachusetts special license plates which also refer to the "Cape and the Islands".

The point is that, irrespective of the formal non-metropolitan designation, economically, geographically, and statistically Dukes and Nantucket are married to Cape Cod which is also known as Barnstable county.

In summary, we believe that Barnstable County should be the proxy for Dukes and Nantucket because:

A. The health data for Dukes and Nantucket strongly correlate to the health data for Barnstable.
B. There is a high correlation between median house prices and SWI and Barnstable comes closest to Dukes and Nantucket
C. CMS should want to use local data rather than provide Medicare reimbursement for one state based on economic data from another.
D. Barnstable County abuts Dukes and Nantucket geographically, separated by only 3 or so miles of the Vineyard Sound.
E. Barnstable and Dukes and Nantucket are considered one region by Massachusetts
F. Barnstable and Dukes and Nantucket have teamed together on federal grants because of the similarity of the economics and demographics further demonstrating the similarity between the counties.
G. The Data is updatable. Once Barnstable is established as the proxy, the data CMS requires is updated annually and meets all of the guiding principle save the one we think is not relevant to the situation. We understand further that the guiding principles are examples of past practices and not statutory in nature.

We suggest that the general rule be:

For any rural county or counties where no PPS data exists the nearest county geographically within the state that can be shown by the affected counties to be similar economically should be used as the proxy for the county or counties without data.

Using a proxy- alternate #2s

We know we have made a strong case for using Barnstable County's SWI as a proxy for Dukes and Nantucket. Further, we believe that we have made a compelling argument that non-rural data could and should be used, especially when it mirrors the rural area(where no data exists) so closely and helps to avoid seeking proxy data from another state.

However, if you examine the data in Chart "A", we believe that if CMS decides that the data must be rural, then the only solution that makes sense to us is to use the rural SWI in Connecticut as a proxy for Dukes and Nantucket Counties.

The data on Chart "A" shows a strong correlation between Massachusetts and Connecticut economically.

A. Massachusetts has the highest housing costs by 11% with Connecticut 2nd more than 25% higher than the next state.

B. Connecticut has the highest per capita money income by 10.8%, but Massachusetts is 2nd.
C. Connecticut has the highest median household income by 7%, but Massachusetts is 2nd .

Since we have showed that our first proxy choice is Barnstable County, it is interesting to note that only in Fairfield County, Connecticut does the housing costs begin to approach the costs in Dukes and Nantucket.

Fairfield County is a metropolitan county with an SWI of 1.2681 which is less than 1/10th of 1% more than the SWI for Barnstable County.

However, the only rural county in New England whose housing costs comes close to the Massachusetts State average housing cost, let alone the housing costs in Dukes and Nantucket County, is Wyndham County, Connecticut.

Wyndham has housing costs of $178,800 compared to $185,700 for the Massachusetts State average or $304,000 for the Dukes County average.

While housing and income data is not "health data", the 2003 "health data', shown again here

	2003 average hourly wage data
Barnstable County, MA	
Falmouth Hospital	$29.68
Cape Cod Hospital	$31.10
Dukes County, MA	
Martha's Vineyard Community Hospital	$29.61
Nantucket County, MA	
Nantucket Cottage Hospital	$31.13

demonstrates the linkage to Barnstable County which has virtually the same SWI as Fairfield County.

The point here is that, as stated early, a mathematical averaging of the New England States' SWI's does not provide a solution to the problem. The diversity of the economics within the New England region argues for seeking a specific state that best approximates the state in question and, where possible, the county seeking a proxy. If CMS insists on providing a rural proxy from another state within the New England region, **then the SWI for Wyndham County, Connecticut is the only choice.**

We look forward to your response to these comments and the final rule.

Regards,

Robert Tonti
CEO-Vineyard Nursing Association
bobtotni@vineyardnursing.org
508-693-6184

CHART_ A

Comparisons of SWI in New England and related data

Data is taken from the 2000 Census State and Xounty Quick Facts.

This chart contains the proposed SWI's (we show the highest SWI's and a range of rural SWI's for each state) within New England states except Rhode Island. We leave out Rhode Island because we argue that the only metropolitan area that should be considered is within the state without PPS data. In this case Massachusetts.

The chart shows:1. the highest SWI's for the county in each state and housing and related data for that county.

2. the SWI's for the rural county(ies) in each state and the corresponding data reflecting the highest and lowest housing data and other related data.

3. Dukes and Nantucket data is listed along side each state for easier comparison.

4. Next to each County data, we provide the State wide averages for that item.

We are attempting to show a strong economic correlation between Barnstables high housing and a high SWI. The same appears to be true for Fairfield county in Connecticut.

Mass			**County owner occupied housing unit-2000**	**State owner occupied housing unit-2000**	**County Per capita money income-1999**	**State Per capita money income-1999**	**County Median household income-2003**	**State Median household income-2003**
	county	**SWI**						
high-metro	Barnstable	1.2561	$ 178,800	$ 185,700	$ 25,318	$ 25,952	$ 47,853	$ 52,713
rural-high	**Nantucket**	**1.0216**	**$ 577,500**	**$ 185,700**	**$ 31,314**	**$ 25,952**	**$ 55,248**	**$ 52,713**
rural-low	**Dukes**	**1.0216**	**$ 304,000**	**$ 185,700**	**$ 26,472**	**$ 25,952**	**$ 49,214**	**$ 52,713**
Conn								
	county	**SWI**						
high	Fairfield	1.2681	$ 288,900	$ 166,900	$ 38,350	$ 28,766	$ 60,881	$ 56,409
rural-only	Wyndham	1.1753	$ 117,200	$ 166,900	$ 20,443	$ 28,766	$ 45,929	$ 56,409
	Nantucket	**1.0216**	**$ 577,500**	**$ 185,700**	**$ 31,314**	**$ 25,952**	**$ 55,248**	**$ 52,713**
	Dukes	**1.0216**	**$ 304,000**	**$ 185,700**	**$ 26,472**	**$ 25,952**	**$ 49,214**	**$ 52,713**
Maine								
	county	**SWI**						
high	Cumberland	0.9926	$ 131,200	$ 98,700	$ 23,949	$ 19,533	$ 47,669	$ 39,212
high	York	0.9926	$ 122,600	$ 98,700	$ 21,225	$ 19,533	$ 47,033	$ 39,212
high	Sagadahoc	0.9926	$ 110,200	$ 98,700	$ 20,378	$ 19,533	$ 44,775	$ 39,212
rural-high	Lincoln	0.8410	$ 119,900	$ 98,700	$ 20,760	$ 19,533	$ 40,791	$ 39,212
rural-low	Aroostook	0.8410	$ 60,200	$ 98,700	$ 15,033	$ 19,533	$ 31,463	$ 39,212
	Nantucket	**1.0216**	**$ 577,500**	**$ 185,700**	**$ 31,314**	**$ 25,952**	**$ 55,248**	**$ 52,713**
	Dukes	**1.0216**	**$ 304,000**	**$ 185,700**	**$ 26,472**	**$ 25,952**	**$ 49,214**	**$ 52,713**
New Hampshire								
	county	**SWI**						
high	Hillsboro	1.0261	$ 139,100	$ 133,300	$ 25,198	$ 23,844	$ 56,182	$ 52,409
high	Merrimack	1.0261	$ 117,900	$ 133,300	$ 23,208	$ 23,844	$ 51,446	$ 52,409
rural-high	Carroll	1.0800	$ 119,900	$ 133,300	$ 21,931	$ 23,844	$ 43,159	$ 52,409
rural-low	Cross	1.0800	$ 70,500	$ 133,300	$ 17,218	$ 23,844	$ 35,201	$ 52,409
	Nantucket	**1.0216**	**$ 577,500**	**$ 185,700**	**$ 31,314**	**$ 25,952**	**$ 55,248**	**$ 52,713**
	Dukes	**1.0216**	**$ 304,000**	**$ 185,700**	**$ 26,472**	**$ 25,952**	**$ 49,214**	**$ 52,713**
Vermont								
	county	**SWI**						
high*	Bennington	0.0994	$ 115,700	$ 111,500	$ 21,193	$ 20,625	$ 40,785	$ 42,649
rural	Essex	0.0994	$ 68,700	$ 111,500	$ 14,388	$ 20,625	$ 31,193	$ 42,649
	Nantucket	**1.0216**	**$ 577,500**	**$ 185,700**	**$ 31,314**	**$ 25,952**	**$ 55,248**	**$ 52,713**
	Dukes	**1.0216**	**$ 304,000**	**$ 185,700**	**$ 26,472**	**$ 25,952**	**$ 49,214**	**$ 52,713**

*The high SWI in Vermont is the rural SWI

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Regulatory Affairs
PO Box 43 Mail Route 10105
Minneapolis, Minnesota 55440-0043

SEP 2 5 2006

September 22, 2006

ALLINA.
Hospitals & Clinics

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program: Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped rental Durable Medical Equipment; Proposed Rule

Dear Dr. McClellan:

On behalf of Allina Hospitals & Clinics (Allina) I appreciate the opportunity to comment on the proposed changes regarding oxygen contents, oxygen equipment and capped rental durable medical equipment. Allina is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. Allina businesses cover the continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, medical transportation, home (or durable) medical equipment and oxygen, pharmacy, home care and hospice services. Allina serves communities throughout Minnesota and western Wisconsin.

I am writing today specific to the needs of Allina Home Oxygen and Medical Equipment (HOME) and the patients we serve through this important part of our business. Allina HOME has provided oxygen, medical equipment and supplies in our community for over 20 years. We are a full service provider carrying a wide array of medical equipment. We serve patients from pediatrics to geriatrics with varying needs, providing oxygen and respiratory equipment, rehabilitation and mobility equipment, specialty beds as well as other medical equipment and supplies. We serve approximately 55,000 patients annually.

Please review our comments below.

Provisions of the Proposed Regulations

The Deficit Reduction Act of 2005

At the outset, we must articulate our overall concerns regarding the impact of shifting the ownership of oxygen equipment from the provider to the beneficiary. We feel that Congress, in its passage of the Deficit Reduction Act, did not thoroughly consider the serious negative effects of requiring the medically frail elderly to own and maintain complex oxygen equipment. It is drastic, unprecedented, and inappropriate to shift oxygen equipment to a rent-to-own model. This change places an unrealistic burden on the patient.

We will be continuing our work to influence our Congressional leaders to make changes in the law. We expect that cost savings projections to the Medicare trust fund due to the shift in ownership will be offset by the increased 911 calls from patients resulting from equipment breakdowns and increased emergency department visits and hospital admissions resulting from too little or too much oxygen.

Oxygen is a life-sustaining Federal legend drug and the devices are dispensed by prescription only. The oxygen technologies used to produce and/or deliver the drug are only by technical components associated with the overall provision of home oxygen therapy. Transferring the burden of maintenance and repair of sophisticated oxygen technologies to the patient and therefore the total management of their home oxygen therapy regimen presents serious risk to patient safety and care. This will clearly produce an undesired effect of unmonitored and unregulated dispensing and distribution of a prescription drug.

The DRA eliminates the Medicare beneficiary's option to continue to use rented durable medical equipment, including equipment used for oxygen therapy. Medicare beneficiaries can, and do, regularly purchase many home medical devices for personal use, but typically not oxygen technologies. However, more often, beneficiaries choose to rent home medical equipment because renting allows for a continuing patient-provider relationship and professional maintenance of complex equipment.

The loss of title to the oxygen equipment will serve as a disincentive for providers to invest in advancing technology. As a result, manufacturers will shift R&D efforts away from the development of smaller, lighter, longer-lasting portable systems and robust low-maintenance technology, instead focusing on the development of cheaper, less-expensive devices. This will lead to a higher probability of equipment malfunction, unacceptable levels of oxygen and increased maintenance and repair costs during the later "useful life" of the equipment.

We are very concerned about the secondary market for oxygen equipment that will come about as a result of people desiring to sell oxygen equipment they no longer have need for. We can envision patients and family members accessing the Internet to purchase needed equipment at lower prices and not having any guarantee of working condition and quality. This creates a major concern for quality and patient safety in the self administration of oxygen therapy. The disposal of owned equipment will also become an issue for family members.

Additionally, the DRA provides no guidance for the myriad service components currently required and incorporated into the Medicare oxygen rules and payment, including all patient training, disposable accessories, billing, clinical professional support, 24-hour emergency service and routine maintenance. The provisions in the proposed rule also do not adequately address these components and we call upon CMS to address these services explicitly.

Routine Maintenance

In the Medicare system today, there are no codes or policies supporting effective and consistent required routine maintenance of oxygen technologies. Routine services are currently provided by the home oxygen providers as part of the monthly rental fee, which will cease upon purchase and transfer of title. We are very concerned about the safety of equipment that is not properly maintained and expect that beneficiaries will not consistently follow through with required routine maintenance. We ask that CMS develop standard protocols for routine maintenance and reimburse providers for providing this service.

A routine maintenance standard and payment should include:

- **Clearly defined frequency for routine maintenance.**
- **Verification of the oxygen purity delivered by the equipment to the patient**. This procedure is performed regularly by a respiratory therapist or specially trained technician using calibrated oxygen analyzing technologies. Without this verification, a patient could be unknowingly receiving sub-therapeutic levels of oxygen. Such an incident may adversely and severely affect the patient's medical condition, requiring emergency care and/or hospitalization.
- **Oxygen dose verification.** Utilizing a flow verification device, a respiratory therapist or specially trained technician regularly verifies the actual prescription being delivered to the patient. Oxygen is a federal legend drug and just as with many other medications, too little or too much, is ineffective and potentially fatal for some patients.
- **Verification of alarm system functions.** This assures the patient, and/or caregiver, will be awakened to place the patient on a back-up oxygen system should the home lose electricity or the oxygen concentrator fail to operate properly.
- **Regular checking of internal and external filter systems**. A respiratory therapist or specially trained technician normally cleans and replaces the filters in accordance with the manufacturer's specifications, often a requirement to retain the manufacturer's warranty.
- **Access to oxygen in cases of natural or man-made emergencies that effect power or damage their homes**. This includes, but is not limited to, 24-hour, seven-day per week on-call and emergency support of all home oxygen patients. A provider commits to providing this level of service when they have a rental agreement with a patient but once the transfer of title takes place, this level of service will not be maintained without appropriate reimbursement. This may set up a tiered service structure with the highest level of service provided to those with rental equipment and a lower level of service for those who own. This means that 24-hour emergency service may not be easily accessible for those who own their equipment and this will lead to increased cost of health care service due to 911 calls or trips to Emergency Department for oxygen.

Although the provisions of the proposed rule do address the accountabilities for service while the equipment is under manufacturer's warranty, we expect that the manufacturers will begin to reduce the length of warranty to stop when the routine maintenance stops at the point of ownership transfer. This will create the potential for significant financial liability to the Medicare beneficiary.

Associated Supplies and Accessories

We ask that CMS develop a payment structure to address provider reimbursement for necessary accessories and supplies when the rental arrangement has been terminated. Disposable oxygen accessories, such as humidifiers, supply tubing, filters, nasal cannulas, trach masks, corrugated tubing, in-line adaptors, and other miscellaneous devices are needed to deliver the prescribed oxygen to the patient. These disposable components require frequent replacement and are included in the current monthly rental fee paid by Medicare. This arrangement will end with the transfer of title and the payment for oxygen contents does not incorporate this expense. If CMS does not support the provider in providing supplies and accessories, you must be clear in all communication with the beneficiaries that supplies are now their expense and will need to be paid for out of pocket.

Access to Beneficiary and Equipment Information

When patients relocate permanently or temporarily, or when they choose a new provider, providers will be put in a position of servicing equipment for which they have not had rental agreements. Therefore, there is no record of rental maintenance or service. In order to support providers to take on this business, it is imperative that the new provider have access to all pertinent information about the equipment and the length of the rental to date. Providers will be very reluctant to enter into rental agreements when the beneficiary is in the middle or near the end of the 36-month timeframe. With a medium- to short-term rental contract there is no way for the provider to capture the investment in the equipment they are now providing the patient. Providers must have access to the Common Working File (CWF) so they can readily validate the length of rental to date as they determine whether or not it is their best interest to provide the equipment. The CWF should also note exactly what equipment the patient owns in order to quickly inform the supplier regarding potential service needs.

We strongly advocate that CMS specify that a new rental period begins whenever a change in supplier takes place regardless of the reason for change. We have major issues currently with how this works concerning capped rental and have major concerns about the administrative burden this will exacerbate with the addition of oxygen equipment and contents. Providers will need additional resources to complete a thorough screening on all new patients, which may delay or limit beneficiary access to oxygen.

New Classes and Rates for Oxygen Equipment and Contents

We appreciate the breakdown of the new classes and rates for oxygen equipment and delivery of contents. We feel strongly that with the new payment structure, providers should have the option to change oxygen modalities. We are penalized for using equipment that may have been appropriate for the patient at the time but, for long-term use, a different modality may be more appropriate. We do not agree that the patient and provider should be locked into equipment that was in the home on December 31, 2005 when we were not aware that the reimbursement structure would be changing.

We do not agree with the heavyweight and lightweight breakdowns for contents. Oxygen contents are the same regardless of the weight of the container to be filled. Providers will use the same amount of resources and fuel regardless of the tank size to be filled. We advocate for one rate for contents.

We would like to suggest that CMS change the word "delivery" to "provision." We are providing oxygen therapy and not just delivering oxygen and equipment. The word "provision" more accurately describes what we do—equipment set up, testing, education, etc., where the word "delivery" would indicate that we just drop off the equipment and leave. In addition, "delivery" may imply that we are required to provide oxygen services at the beneficiary's residence. This may not always be possible given the proposed reimbursement rates.

Equipment Breakdown and Reasonable and Necessary Service

We would like to propose a redefinition for "labor." Our costs begin when the service technician leaves our facility and ends when they arrive back to the shop. We seek a redefinition to clarify that the labor time charge is from portal to portal and not just for skilled technician time in the home or in the shop.

Final Comments

On behalf of our Home Oxygen and Medical Equipment business, Allina sincerely appreciates the opportunity to provide feedback on these proposed changes. We are very concerned that vulnerable patients and their families are being put in a very difficult situation as CMS tries to manage cost and address the issues with poor quality DME providers. The focus of the DRA is misplaced and will create unintended consequences that will be detrimental to patients and to the health care industry as a whole. We sincerely hope that you give serious consideration to our comments. We look forward to the seeing the impact of our comments in the final rule. Please feel free to contact me if you have questions. I can be reached at 612-262-4912.

Sincerely,

Nancy G. Payne

Nancy G. Payne, R.N., M.A.
Director Regulatory Affairs

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JOHNSTON LAW FIRM

SEP 2 5 2006

CHRISTOPHER C. JOHNSTON
e-mail: johnstonlawfirm@bellsouth.net

September 21, 2006

BY: UPS Overnight

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comment to Home Health Prospective Pay System

Rate Update for Year 2007
CMS – 1304 - P

To Whom It May Concern:

I am submitting this comment on behalf of a number of home health agencies located in the State of Louisiana. In particular, these agencies are concerned about the percent change in the PPS wage index for Southeast Louisiana (CBSA code 12940) including East and West Baton Rouge Parishes (SSA state/county codes 19160 and 19600), neighboring Livingston and Ascension Parishes (SSA state/county codes 19310 and 19020), and Orleans Parish (SSA state/county code 19350) as reflected in the addendum C to the proposed rules for the years 2006-2007. While the wage index for most of the parishes in the State of Louisiana remain stable or increase slightly for CY 2006-2007, the wage index for East and West Baton Rouge, Ascension and Livingston Parishes falls a dramatic 6.02% while Orleans Parish falls 1.52%. (See Federal Register Vol.71, No. 149 at page 44148).

Following Hurricane Katrina's devastation of Southeast Louisiana in August 2005, there have been significant professional nursing and other clinical staff shortages causing, if anything, increases in wages paid by health care providers including hospitals from which the wage index numbers are derived.

Accordingly, there is a concern that the calculation of the wage index for these Parishes, as reflected in the proposed rules, are not accurate and we respectfully request that CMS review all applicable data concerning the wage indexes reported for these parishes and confirm its calculations prior to the issuance of the final rule.

We thank you for your kind consideration of this request and comment.

Very truly yours,

Christopher C. Johnston

11816 Sunray Ave, Suite "A"
Baton Rouge, LA 70816

Phone: (225) 295-8336
Fax: (225) 293-7666

September 15, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
PO Box 8014
Baltimore, MD 21244-8014

Re: File Code CMS-1304-P

Dear Sirs:

The Home Care Alliance of Massachusetts (HCA), on behalf of our member home health care agencies, appreciates this opportunity to submit the following comments on the proposed rule for the FY 2007 Home Health Prospective Payment System Rate Update.

PROVISIONS OF THE PROPOSED REGULATIONS

A. National Standardized 60-Day Episode Rate

We are concerned that, after five years under the prospective payment system for home health, CMS has proposed no adjustments to the case mix weights upon which the 60-day episodic payments are based. We believe that CMS has by this time accumulated enough utilization data that some fine-tuning of the case mix weights is possible. **We urge CMS to undertake such a review and make appropriate adjustments to the case mix weights prior to 2008**, to ensure that agencies are reimbursed appropriately for patients across the case mix spectrum.

D. Outcomes Data Submission

We are encouraged that CMS has proposed an initial step toward incorporating a "Pay for Performance" component into the Medicare home health reimbursement system. However, we find it disconcerting that CMS has proposed a 2% payment penalty for agencies that do not submit OASIS Outcomes data, without any incentives on the other side of the equation. Our

understanding is that "Pay for Performance" includes both incentives and penalties. Your proposal has a stick, but no carrot! CMS estimates that less than one percent of agencies and claims will be affected by this rate reduction. If one percent of all claims are reduced by two percent, the total net reduction to the Medicare home health system will be approximately $1.8 million. **We strongly recommend that the national standard episode amount be increased to make this penalty budget neutral and provide a small reward for the majority of agencies that already comply with the data submission requirement.**

F. (3) Hospital Wage Index – Labor Market Areas

We have serious concerns about CMS's proposed wage index for Rural Massachusetts. In the proposed rule, CMS states that Rural Massachusetts was one of three "geographic areas where there were no hospitals, and thus no hospital wage data on which to base the calculation of the ... home health wage index." That assertion is not accurate. There are, in fact, two hospitals in rural Massachusetts (Martha's Vineyard Hospital and Nantucket Cottage Hospital), but they are Critical Access hospitals (CAHs). In August, 2003, CMS announced a policy decision to eliminate CAHs from the wage index calculation for inpatient PPS hospitals, and, as a consequence, all other Medicare provider types whose wage index is calculated from inpatient hospital wage data.

CMS proposes to "freeze" the wage index for Rural Massachusetts at 1.0216 – the same level it has been at since 2005, the year after CMS decided to remove CAHs from the wage index calculation. This proposed wage index is based on 2004 wage data from Franklin Medical Center in Franklin County in Western Massachusetts. With the transition from MSAs to CBSAs as the basis for Medicare wage index, Franklin County is now part of the Springfield, MA, CBSA. In other words, CMS's proposed wage index for rural MA is based on OLD data from a single hospital that is no longer even considered Rural. Furthermore, the average hourly wage data from Franklin Medical Center has consistently been far lower than the average hourly wage data for Martha's Vineyard and Nantucket Cottage hospitals. For example, the Inpatient Hospital PPS update published by CMS in the *Federal Register* on August 11, 2004, reported the following average hourly wages for FY 2003:

Franklin Medical Center	$24.62
Nantucket Cottage Hospital	$31.13
Martha's Vineyard Hospital	$29.61

(This is the most recent comparative data available because CMS removed Critical Access Hospitals from the wage index calculation after 2004.) This data indicates that the average hourly wages for Nantucket Cottage Hospital and Martha's Vineyard Hospital are 26.4% and 20.3% higher, respectively, than the average hourly wage for Franklin Medical Center.

For 2005, the three home health agencies in Nantucket and Dukes Counties received combined Medicare reimbursements of $1,637,382. The cost to provide those Medicare services was $2,037,580, for a net loss from Medicare services of $400,198 (19.64%). If the wage index for Rural MA is frozen at 1.0216 for 2007, we estimate that the losses for these agencies will increase to $507,880 (23.34%).

Clearly, there is no statistical justification for continuing to use the wage data from Franklin Medical Center to set a wage index for Nantucket and Duke's Counties.

In the proposed rule, CMS recognizes that the 1.0216 wage index is an imperfect solution, and has solicited alternative methodologies. CMS identifies four "basic policy criteria" that alternatives should adhere to: 1. based on "pre-floor, pre-reclassified hospital wage data;" 2. based on rural wage data; 3. easy to evaluate; and 4. updatable from year to year. **To these four criteria, we would add a fifth, which we believe is the underlying principal behind the entire wage index, and should take precedence over all other criteria: 5. the wage index should be based on the most locally applicable data available.** We agree that an ideal solution would meet all five of these criteria, but if no such solution is possible, criterion 5 must be given extra weight in evaluation the available options.

The wage index that CMS has proposed for Rural MA meets only 2 of these 5 criteria, and should be rejected.

CMS has described one alternative in the proposed rule which would calculate an "imputed" wage index for rural MA based on the average wage index of the rural areas in four other states in the New England Census Division. **We strongly object to this alternative, as it is based on regional rather than local data that have no more applicability to Dukes and Nantucket Counties than the current practice of using two-year-old data from Franklin County.**

A review of wage data from the Bureau of Labor Statistics demonstrates that the economy in rural MA (Dukes and Nantucket Counties) is significantly different from the economy in rural areas of other New England states. For example, the following BLS data show average annual salaries in the Health care and social assistance sector for representative rural counties in the various New England states in 2005:

Windham County, CT	$34,211
Aroostook County, ME	$27,032
Dukes County, MA	**$42,281**
Nantucket County, MA	**$45,482**
Cheshire County, NH	$33,261
Lamoille County, VT	$32,723

(We are using wage data from the entire health care and social assistance sector as a proxy for this comparison because hospital-specific data is not available from BLS for many of these areas.) This BLS data shows that the average wage in the health care and social assistance sector in the two rural MA counties is $43,882 – **38.0% higher** than the $31,807 average of the representative rural counties in the other New England states. **It is clear from this data that the rural areas of Connecticut, Vermont, New Hampshire and Maine are not appropriate proxies for setting a wage index for rural Massachusetts.** ***We strongly recommend that CMS not adopt this alternative methodology.***

We believe that CMS's decision in 2003 to exclude wage data from Critical Access Hospitals in calculating the wage index for home health agencies and other non-hospital Medicare providers will come to be a major problem for CMS in coming years. For 2007, there are only three areas of the country that do not have wage data from local PPS hospitals to be used in calculating a wage index: Rural Massachusetts, Rural Puerto Rico, and the Hinesville, Georgia CBSA. However, given the extremely rapid growth in the number of hospitals around the country that have critical access status (there are now over 1,200 CAHs nationally) there will surely be additional CBSAs and rural areas in this situation in coming years.

To address this problem in the long term, we strongly urge CMS to go back to its practice prior to 2003 of including wage data from CAHs in calculating the wage index for non-PPS-hospital providers.

In recognition of the fact that CMS cannot make such a sweeping policy change in time to adjust all wage indices for the 2007 calendar year, we have developed four options to address the problem in the short them for the Rural Massachusetts wage index for 2007. In descending order of preference, those options are:

1. Our preferred short-term recommendation is that **CMS recalculate the Rural MA wage index using wage data from the CAHs in rural MA. If recent wage data from these CAHs is not readily available, we strongly recommend that CMS use the wage data from 2003 for these hospitals to calculate a local wage index for 2007.** According to our calculations, this would result in a wage index for Rural MA of approximately 1.3361. The net impact on overall Medicare spending on home health care would be an increase of under $400,000 (less than 1/100 of 1%), and these agencies would still face a combined estimated loss of 5.13% on their Medicare services.

2, Our second alternative is that **CMS establish a general policy to calculate a proxy wage index for any Rural area or CBSA without hospital wage data by using the Average wage index of all CBSAs contiguous to that area.** For Rural Massachusetts, the proxy would be the wage index for Barnstable County (1.2561), since that is the only contiguous area to Nantucket and Dukes Counties. BLS wage data and CMS's hospital wage data both show that Barnstable County would be a reasonable proxy for Rural MA. Using the same BLS data that we cited above, the average annual salary in 2005 within the Health care and social assistance sector in Barnstable County was $38,520. The average for Rural MA ($43,882) is still 13.9% higher than Barnstable County, but this is a much closer proxy than CMS's proposal to use Census Division data. Wage data from the hospitals in Dukes and Nantucket Counties has consistently been far more similar to wage data for the two hospitals in Barnstable County than to Franklin Medical Center. The August 11, 2004, Federal Register notice lists the following average hourly wages for 2003:

Falmouth Hospital	$29.68
Cape Cod Hospital	$31.10

While this proposal to use the average of the wage index for all contiguous CBSAs does not use rural data, it meets all of the other criteria CMS has established. More importantly, it has the advantage of using the most local wage data available from PPS hospitals.

3. Use the **rural wage index from the single state closest to the MA rural area.** Since Rhode Island has no rural areas, the closest state with a rural area is Connecticut. The wage index for Rural CT is 1.1753. This option has the advantage of meeting all of CMS' four criteria, plus it is more local than the Census Region average in CMS's "alternative" proposal.

4. Use the **same methodology that CMS currently uses to calculate an "imputed rural floor" for PPS hospitals in states with no Rural areas**. Under this established methodology, CMS calculates the average wage index of all CBSAs within the state and uses that figure as a rural floor. For Massachusetts, the PPS-hospital imputed rural floor is 1.0664. We note, however, that this methodology does not use rural wage data and is not local, so would be our least-favored alternative.

We have attached to our comments a spreadsheet outlining the financial impact of each of these various options, along with a summary of how well each of them complies with the five policy criteria. From this analysis, it is clear that **the option that most closely complies with the five policy criteria – and that could establish a simple policy precedent going forward to prevent this situation from occurring in additional areas in the future -- is for CMS to return to its previous policy of including wage data from Critical Access Hospitals in calculating the wage index for home health and other non-PPS hospital providers.**

Thank you for this opportunity to comment. We would be happy to discuss our recommendations further.

Sincerely,

Timothy Burgers
Associate Director

MA Rural Wage Index

	2005	**2007	2007 CMS Regional Alt.	***2007 Critical Access	2007 Barnstable	2007 CT rural	2007 Hospital Rural Floor
Wage index	1.0216	1.0216	1.0227	1.3361	1.2561	1.1753	1.0664
*Medicare Reimbursement	$1,637,382	$1,668,492	$1,669,827	$2,064,759	$1,963,982	$1,862,204	$1,724,887
*Medicare Costs	$2,037,580	$2,176,372	$2,176,372	$2,176,372	$2,176,372	$2,176,372	$2,176,372
*Medicare Loss	-$400,198	-$507,880	-$506,545	-$111,613	-$212,390	-$314,168	-$451,485
Percent loss	-19.64%	-23.34%	-23.27%	-5.13%	-9.76%	-14.44%	-20.74%
$ impact Medicare Expense			$1,335	$396,267	$295,490	$193,712	$56,395
****CMS criteria		A,C	A,B,C,D	A,B,C,D,E	A,C,D,E	A,B,C,D	A,C,D

*Data on Medicare Reimbursement, Costs, and Loss are based on combined 2005 data from the three home health agencies in Dukes and Nantucket Counties.
**2007 Costs are estimates based on 2005 costs updated by CMS's home health market basked inflation adjustments for 2006 and 2007.
***Estimate based on analysis by Besler Consulting.
****In the 8/3/06 proposed rule, CMS lists four policy criteria to evaluate methodologies:

A: use pre-floor, pre-reclassifed hospital wage data;
B: use rural wage data;
C: easy to evaluate;
D: updatable from year to year.
E: to those criteria, we propose a fifth: local

8

UnitedHealthcare®
A UnitedHealth Group Company

5901 Lincoln Drive Edina MN 55436

September 13, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: UnitedHealthcare comments submission regarding:
Federal Register / Vol. 71, No. 149 / August 3, 2006 / Proposed Rules / pages 44082-44180,
Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule)

Dear Sir or Madame:

Following your invitation UnitedHealthcare submits the attached comment on the referenced **Federal Register** publication regarding proposed Changes to Medicare Payment for Oxygen Equipment.

The opportunity to participate in this forum is appreciated.

Sincerely,

Michael Ile, Vice President Network Management
UnitedHealthcare
5901 Lincoln Drive, MN012-S204
Edina, MN 55436
(952) 992-7384
Fax: (952) 992-4320

Enclosure: One original and two copies

CC: Robert Holman, Director, Pricing Schedule Management
Steve Affield

Comment on [PERIODS OF CONTINUOUS USE] in reply to CMS question:

Should a new period of continuous use cap rental period begin for new or additional equipment prescribed by a physician and found to be medically necessary, even if the new or additional equipment is similar to the old equipment?

UnitedHealthcare comments

Assuming no clinical reason exists for a change in oxygen equipment, only one physician writing the initial prescription for oxygen should initiate each 36 month rent to own period. Subsequent prescriptions by the same or other physicians should not start new 36 month rent to own periods.

AMERICAN ASSOCIATION FOR RESPIRATORY CARE
9425 North MacArthur Blvd., Suite 100, Irving, TX 75063, (972) 243-2272, Fax (972) 484-2720
http://www.aarc.org, E-mail: info@aarc.org

BY HAND DELIVERY

September 22, 2006

SEP 22 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: **CMS-1304-P – Home Health Medicare Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment: Proposed Rule**

Dear Dr. McClellan:

On behalf of the American Association for Respiratory Care (AARC), I am pleased to submit comments on the proposed rule published in the *Federal Register* on August 3, 2006, to update the home health prospective payment rate for calendar year 2007 and to implement provisions of the Deficit Reduction Act (DRA) of 2005 regarding Medicare payment for oxygen and oxygen equipment and capped rental durable medical equipment. The AARC is the national professional association representing over 40,000 respiratory therapists who treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis.

The AARC is most concerned with the health and safety of Medicare beneficiaries who are on long-term oxygen therapy. We recognize that the Centers for Medicare and Medicaid Services (CMS) has no leeway in implementing the DRA provisions that mandate transfer of ownership of oxygen and oxygen equipment to the beneficiary after 36 months of continuous use; however, we are nonetheless worried about those beneficiaries who may not be able to undertake routine maintenance and repair on their own due to various physical and mental impairments.

While CMS has taken certain safeguards to protect Medicare beneficiaries once transfer of ownership takes place, we believe the proposed rule falls short of fully recognizing the dangers to Medicare beneficiaries' health and safety that may be a consequence of the responsibilities they must now assume as owners of the oxygen equipment.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ► 1

To	Maggie Peters	From	Tuli Mirra
Dept./Agency	CMS/OSORA/RegsC	Phone #	410-786-0148
Fax #	410-786-3004	Fax #	202-205-9537

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

Recommendation 2

CMS should require suppliers to re-train beneficiaries (and/or their caregivers) on the services they will need to perform on the equipment at the time they transfer ownership and to verify in writing that the beneficiary/caregiver has actually performed the tasks for which they will be responsible to ensure that they are capable of doing so.

As evidenced by the FDA adverse event reports, patients do not always understand the instructions they are given about the safety and hazard aspects of their oxygen equipment, nor do they necessarily follow them. While qualified professionals, often respiratory therapists, provide basic training and instructions at the time of set up, there are no assurances or a requirement for verification that the beneficiary understands the instructions or is able to perform certain routine functions short of actually demonstrating that they can do so. Once beneficiaries own their oxygen equipment, it will become even more important they understand their ownership responsibilities and are able to perform them.

CMS states in its proposed rule "We expect that the supplier, when transferring title to the equipment to the beneficiary, would also provide to the beneficiary any operating manuals published by the manufacturer which describe the servicing an owner may perform to properly maintain the equipment." We recommend that CMS add an additional safeguard in §414.226 (g) by requiring the supplier at that the time of transfer to re-train the beneficiary and/or caregiver with respect to information regarding preparation of formulas, features, routine use, troubleshooting, cleaning, maintenance, safety considerations, and infection control.

These requirements are currently contained in the DME Quality Standards; however, the supplier is only required to verify that the beneficiary received the instructions and information at the time of setup, not they he or she understood them or could perform them. The fact that instructions were provided is meaningless unless the person(s) receiving the instructions is capable of carrying them out. Further, if the beneficiary does not perform routine checks and maintenance soon after being provided the instructions, it is likely that they will be forgotten or misunderstood when it time to actually perform them. During the rental period, the beneficiary often relies on the professional expertise of the supplier to ensure that proper servicing and maintenance is performed. Re-training the beneficiary at the time of transfer and **verification in writing** by the supplier that the beneficiary and/or caregiver can actually carry out the tasks could prevent serious injuries or even life-threatening situations in the future.

- **CMS' assumption that beneficiaries will be fully knowledgeable about the routine servicing and maintenance of their equipment by the time ownership transfer occurs has been oversimplified.**

CMS maintains that after receiving the manufacturer's information about their equipment, and "after becoming familiar with the equipment during the 13- or 36-month rental period, the beneficiary or caregiver should be very knowledgeable regarding the routine maintenance required for the item." The AARC strongly disagrees with this assumption. We believe it is highly unlikely that the average Medicare beneficiary

profiled earlier in our comments will have the wherewithal to effectively remember all of the complicated routine checks and servicing required for ensuring proper functioning of the various types of oxygen equipment prescribed by their physician.

It cannot be overstated that equipment utilized to deliver home oxygen therapy is technically complex and varies based on the type, brand and model used to deliver the prescribed liter flow. Although each manufacturer may have unique specifications for the various types and models it produces, there are a number of common issues associated with the management of home oxygen technologies, including but not limited to the items outlined below.

- Oxygen concentrators are an electrically operated, mechanical gas filtering and separation system that must be cleaned and checked regularly for the system to operate correctly. Over time, the sieve beds (nitrogen filters) eventually deplete or become contaminated, greatly reducing the ability to absorb nitrogen, and therefore, inhibiting the ability to produce a therapeutic level of prescription oxygen. Currently, home medical equipment providers are obligated to ensure the safety and performance of the oxygen devices they rent.

- Compressed gas cylinder systems, which are commonly used for emergency back-up and portability, use a regulator or pulse-dose oxygen delivery device (e.g., an oxygen conserving device) to deliver oxygen to the patient. The cylinders have a very limited supply of oxygen that depletes quickly (i.e., a few hours) as the patient utilizes the contents of the tank. Compressed gas cylinders need to be refilled frequently. In addition to regular re-filling, all compressed gas cylinders must undergo periodic safety testing as mandated by the Department of Transportation (DOT) and FDA.

- Liquid oxygen systems, which often utilize electronic or pneumatic pulse dosing systems to deliver the prescribed oxygen liter flow, require consistent refills, even if not used. If the oxygen equipment is purchased for the patient, a home liquid oxygen system will still require refilling 2 to 5 times per month, depending on the patient's oxygen prescription and the type of system. Liquid oxygen is a hazardous material and the DOT and FDA closely regulate the transport and home filling liquid oxygen system.

Any malfunction, misuse, or failure of the equipment and/or supplies may result in a non-therapeutic oxygen percentage or inappropriate oxygen liter flow, compromising the physician's prescription and goal to maintain the patient's stable condition. Ineffective treatment will result in the deterioration of the patient's condition (in some cases a sudden and rapid exacerbation.) Without routine equipment maintenance, monitoring the equipment will become increasingly ineffective and/or suddenly cease to operate. Either scenario places the patient in a potentially unrecognized, yet significantly, compromised position.

Under the rental-type arrangement, necessary and routine maintenance and servicing of the oxygen equipment is currently performed by the supplier and covered and paid for in the monthly rental fee. Beneficiaries have relied on these professional services and trusted their expertise to ensure the safe and effective use of their equipment. Because of the complexities of various types of oxygen equipment, the AARC does not believe that the patient will be as knowledgeable about their equipment as CMS surmises when it comes to knowing what they will be expected to take care of once they own the equipment. This is particularly true for those beneficiaries that use more than one type of equipment and suffer from various disabilities and forms of cognitive impairment.

Recommendation 3

CMS should require the supplier to provide the beneficiary with a list of "routine" services for which Medicare will no longer make payment once title of the equipment transfers to the beneficiary.

The AARC recommends that CMS add an additional safeguard in §414.226 (g) that requires the supplier to put in writing the services they will no longer perform under the new provisions and for which the beneficiary will now be responsible. This requirement could be simplified by the development of a standard format for each type of equipment that the supplier need only check off the list. There should be no doubt in the beneficiaries mind as to what they need to do to maintain the equipment, because any negligence on their part could have serious repercussions. We request that CMS discuss this issue more fully and provide additional information in the final rules.

In addition to the above recommendation, we suggest that suppliers maintain on their websites, or CMS on its "Medicare.gov" website, the same type of checklist; that is, routine periodic services that Medicare will no longer cover once title of the equipment transfers to the beneficiary and that the beneficiary will be expected to perform on his or her own. We have listed above various services that are currently performed and are frankly unclear which ones CMS will determine are "routine." We believe there will be much confusion during the transition phase and the fact that the beneficiary and/or caregiver can access information in more than one place or format can be helpful. We recognize, of course, that a significant number of the Medicare beneficiaries on long-term oxygen are too sick and disabled to undertake or even understand computer technology. That is why we feel is it essential for suppliers to provide beneficiaries at the time of title transfer a written checklist of their services for which Medicare will no longer provide payment.

As discussed above, we believe there will be many instances where a beneficiary simply will not be able to undertake the routine services for which they will now be responsible in order to properly maintain their oxygen equipment. Since Medicare will not pay for services such as "testing, cleaning, regulating, changing filters and general inspection" of the equipment, the beneficiary needs to be clearly informed as to what this means in the way of responsibilities that they will now have to provide that were heretofore performed by the HME supplier. For a variety of reasons, not the least of which are safety concerns, we believe that a number of beneficiaries may elect to hire a third party to perform these

types of routine tasks rather than attempt to undertake such services themselves. In those cases, the beneficiary needs to understand clearly that they must bear the cost.

The underlying factors behind the changes in payment for oxygen and oxygen equipment are that Medicare has continued to pay for equipment well past its initial cost and, as a result, beneficiaries have continued to pay unnecessary coinsurance as part of the rental fee. Under the proposed changes, the government will no longer spend money over and above what it originally would have paid, nor will beneficiaries have to pay the monthly co-payment amount for the rental e.g., around $40 per month. While the assumption is that everyone saves, the AARC believes the reality will be that some Medicare beneficiaries could end up spending more once they own their own equipment. The potential for this scenario only adds to their already stressful burdens.

General Comments Regarding Changes to Payment for Oxygen and Oxygen Equipment

- **The proposed rule does not provide enough clarity and specificity for stakeholders and Medicare beneficiaries alike to fully recognize the impact on Medicare beneficiaries when the final provisions become effective.**

Given the recent changes in the Medicare program with respect to the new provisions for prescription drug coverage under Medicare Part D, Medicare beneficiaries have been inundated with information and the need to make informed decisions. Now they will be asked to understand their new responsibilities for taking care of their oxygen equipment. Granted, the process will not become effective until 2009 at the earliest, but the complexity of oxygen equipment and the services associated with it, including the fact that each different type of equipment carries with it different safety and routine maintenance requirements, will surely be overwhelming for the average Medicare beneficiary receiving long-term home oxygen therapy to comprehend.

Recommendation 4

CMS should develop a list of "Frequently Asked Questions" specific to oxygen and oxygen equipment payment to assist beneficiaries in understanding the significance of the new provisions and their impact on the beneficiary.

We recommend that CMS develop a specific category of "Frequently Asked Questions" directly related to oxygen equipment on its "Medicare.gov" web site. We have attached a list of questions (**see Appendix A**) that cover some of the issues that we believe will be of interest to beneficiaries once the new payment for oxygen and oxygen equipment provisions become final. Of course, we expect this listed to be expanded as additional questions and issues occur.

Summary

Implementation of the DRA provisions affecting payment for oxygen and oxygen equipment can have significant consequences for Medicare beneficiaries on long-term home oxygen therapy. The physical and mental capacity of these patients and the potential health and safety risks that could occur once they own their own equipment are key issues that need to be addressed.

Beneficiaries on continuous oxygen, most of who suffer from COPD, are elderly and very sick patients who are unable to carry out many of the normal activities of daily living. Further, serious cognitive impairments can cause an inability to understand the complex instructions and need for routine maintenance and servicing that heretofore have been performed by highly professional and trained personnel. Unlike other DME, various types of oxygen equipment are technically complex and carry with them strong warnings of safety hazards. Serious injuries or even life threatening situations can occur if the beneficiary is not able to understand or perform correctly the routine services they may have to undertake in the future.

In the proposed rule, CMS has added certain safeguards to protect Medicare beneficiaries once transfer of ownership takes place. We believe these requirements fall short of fully recognizing a variety of unintended consequences that may result once the provisions become final. For example, there is no requirement that the supplier continue to service the beneficiary's equipment once title of ownership transfers to the beneficiary or a timeframe by which the supplier should notify the beneficiary of change. In these situations, CMS should add additional safeguards to ease the transition by requiring the supplier to notify the beneficiary at least 3 months in advance of transfer if they are not going to keep servicing the equipment. We believe it is reasonable for the beneficiary to have an adequate amount of time to find another comparable supplier without leaving a potential gap in coverage.

AARC is most concerned about the physical and mental capabilities of patients on long-term oxygen use to perform even the most menial tasks. Of particular concern, is the beneficiary's ability to perform routine servicing once they own their oxygen equipment. Instructions and training on their equipment are only currently provided only at the time of set-up and delivery and the beneficiary is not required to demonstrate use of the equipment once they are trained. Therefore, we recommend that CMS require the supplier to re-train the beneficiary on use of their equipment at the time of transfer as an additional safeguard. Also, at that time, CMS should require the supplier to verify in writing that the beneficiary is capable of performing the required routine maintenance by having the beneficiary/caregiver actually perform the tasks.

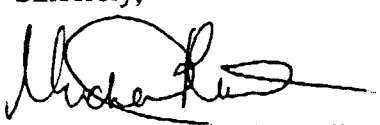
Although the new oxygen payment provisions are supposedly designed to save money for the Medicare program and the beneficiary as well, we believe a number of beneficiaries may hire a third party to perform the routine maintenance tasks that will otherwise transfer to the beneficiary to ensure there is no chance for error that could result in serious injury or death. In the end, these beneficiaries may likely pay more for home oxygen therapy than they are paying under the current provisions.

CMS states that the beneficiary should be fully knowledgeable about their oxygen equipment after 36 months of continuous use (or 13 months for capped rental). AARC disagrees with this assumption. We believe there will be a lot of confusion about what is and is not covered once transfer occurs. Therefore, we recommend CMS require suppliers to provide the beneficiary with a written list of which services Medicare will no longer pay for once transfer of ownership is complete. This information should also be posted on the supplier's website or even the "Medicare.gov" website.

The proposed rule leaves a lot of questions to be answered. We highly recommend that CMS provide additional detail in the final rule in defining "routine services" for oxygen equipment. Oxygen equipment is more complex that other types of DME and some services that may be considered "routine" should continue to be performed by trained and professional personnel. It would also be helpful for CMS to establish on its "Medicare.gov" website a list of "Frequently Asked Questions" that pertain specifically to payment for oxygen and oxygen equipment. This action can assist beneficiaries (and caregivers) in knowing how the new provisions may affect them in the near future. AARC has provided an initial list of questions for CMS' consideration.

We appreciate the opportunity to provide these comments and hope that CMS will consider our recommendations to ensure beneficiaries' health and safety are protected once final regulations become effective. If you have any questions about our comments or desire additional information, please call Cheryl West, Director of Government Affairs, at 972-243-2272.

Sincerely,



Michael Runge, BS, RRT
President

APPENDIX A

List of Frequently Asked Questions

1. How do I know if the oxygen concentrator is functioning properly and is putting out the correct amount of oxygen?
2. If I call my supplier and it is not time for Medicare to pay for servicing, will I have to pay the supplier? How much can the company charge me?
3. Are pocket flow meters that determine adequate oxygen flow for concentrators considered a covered supply?
4. How do I know if my humidifier is working correctly? It is plastic and wears out. Will I have to pay for the replacement of it or is that a supply that Medicare will pay for?
5. Who do I call if the electricity goes out and my concentrator stops working? Will I have to pay for the supplier to bring in a backup? Will I have to pay for the backup equipment? How long could I keep the backup equipment?
6. If I live with someone who smokes tobacco or I live in a high pollution area, I will have to change out the cotton filters more than the recommended 3 months, probably every month. Will Medicare cover the cost of the new filters when the changes are required this frequently?
7. I spend several months a year away from my primary residence. Do I need to pack up my oxygen equipment and ship it to my temporary residence? Will another supplier at my destination provide me my oxygen equipment? Will I have to buy it from them, or can I rent it from them? Will Medicare cover any of these costs? How much can the supplier charge me if I have to rent it?
8. While I am away from my primary residence, will Medicare still cover the supplies from the supplier I am using temporarily?
9. What if my medical condition changes and I need a different type of oxygen equipment? Will I be able to get it? Will I have to pay for it, or will the 36-month rental period start again?
10. How will I be assured that I have the information I need to take care of my equipment?
11. Will my supplier have a 24-hour hotline in case I need assistance after normal business hours?
12. Can I hire another company to take care of the routine maintenance on my oxygen equipment if I cannot take care of it myself as long as I pay for the service?
13. How will I know which services Medicare will pay for once I own my own equipment?
14. Will my supplier continue to service my equipment once I own it? If not, how will I know to find another supplier?

10

SUBMITTED ELECTRONICALLY

September 25, 2006

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Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76

Dear Dr. McClellan,

Invacare Corporation (Invacare) appreciates the opportunity to submit comments to CMS on the Notice of Proposed Rulemaking, Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payments for Oxygen Equipment, and Capped Rental Durable Medical Equipment (CMS-1304-P). Based in Elyria, Ohio, Invacare is the largest manufacturer of home respiratory devices in the United States, including oxygen concentrators, portable oxygen tanks, and oxygen generating portable equipment.

Deleted: global leader

Deleted: manufacture of the broadest product offering of innovative home medical equipment (HME) that promotes recovery and active lifestyles. Among the products we manufacture and sell to HME providers are a broad array of respiratory devices

Overall Comments

Invacare Corporation commends CMS for its recognition of the many benefits that oxygen generating portable equipment can provide. It provides patients with the mobility and convenience they desire, it provides physicians with the understanding that their patients always have access to ambulatory oxygen, and it provides costs savings to the health care system. While CMS' proposed rule appropriately provides some financial incentives for providers to provide oxygen generating portable equipment, CMS should ensure that its policies create no obstacles to beneficiaries with medical need for portable home oxygen therapy from receiving oxygen generating portable equipment.

For example, patients should be able to transfer to these systems at any time; without any financial disincentives for providers. If a patient wishes to transfer to oxygen generating portable equipment at a point when he/she is well towards the 36 month rental cap, there are financial barriers due to the significantly larger capital investment required for these

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Summary of Comments¶
CMS' proposed regulation implements, in part, the mandates of the Deficit Reduction Act (DRA) and its mandate that beneficiaries be forced to assume ownership of oxygen equipment after 36 months, and that monthly rental payments for home oxygen equipment be capped at 36 months. The thinking behind the DRA fails to understand the range of administrative, support, emergency, clinical and other services that providers furnish to beneficiaries, services which are integrally related to the ability of the beneficiary to receive a clinically effective home oxygen therapy regimen. CMS has taken an overly restrictive position of what the home oxygen therapy benefit entails, and what is necessary to ensure that the beneficiary receives the most clinically efficacious home oxygen therapy.¶

Formatted: Justified

[1] Pub. L. 109 -171 (2006).

Invacare Corporation
600 Cameron Street
Alexandria, VA 22314

Item Group	Item #	Item Description
WHEELCHAIR PARTS	8881127510	KIT ARMPAD DESK W/2 SCREWS CLR
WHEELCHAIR PARTS	1004310	POSITION STRAP AUTO STYLE 45IN L 9153605929
WHEELCHAIR PARTS	1058649	CASTER 8 IN CMPST URETHANE 9153633236
WHEELCHAIR PARTS	8881127525	KIT SEAT UPH 18WX16D W/HDWR
WHEELCHAIR PARTS	1110817	ARM PAD DESK WTRFL W/HDWR PAIR 9153637618
WHEELCHAIR PARTS	1127533	KIT SEAT 18WX16D W/HDWR U240
WHEELCHAIR PARTS	1034216	TRANSFER BOARD 9153622747
WHEELCHAIR PARTS	1110818	ARM PAD WTRFL FULL W/HDWR PAIR 9153637617
WHEELCHAIR PARTS	1058836	ANTI-TIP REAR 8 IN FK+CSTR PR 9153629600
WHEELCHAIR PARTS	8881127509	KIT ARMPAD FULL W/2 SCREWS CLR
WHEELCHAIR PARTS	1035971	KIT 2 IN SEAT EXTENSION 2 EACH 9153623602
WHEELCHAIR PARTS	1064476	WHEEL OPTION URE 20-6/DK GREY
WHEELCHAIR PARTS	1098818	WHEEL ASBLY H-D 24 IN
WHEELCHAIR PARTS	1075460	WHEEL 8X1 DK GREY CMPST SOLID
WHEELCHAIR PARTS	1058836	ANTI-TIP REAR 8" FORK+CSTR PR 9153629600
WHEELCHAIR PARTS	1038599	WHEELLOCK EXTENSION 6 IN 2 EACH 9153625347
WHEELCHAIR PARTS	1080378	WHEEL CMPST URETHANE 24X1" 9153635461
WHEELCHAIR PARTS	1080379	WHL CMPLT 24 IN URE W/HNDRM 7/16
WHEELCHAIR PARTS	1117328	ARMPAD FULL WTRFL W/HDWR 9153641617
WHEELCHAIR PARTS	1099557	1-ARM DRIVE AD3W/URE 18 INW RT
WHEELCHAIR PARTS	1127534	KIT SEAT 18WX18D W/HDWR U240
WHEELCHAIR PARTS	1115397	HANDRIM 7PT 24 INWH BLK PLST CTD 9153641615
WHEELCHAIR PARTS	1074471	CABLE AND HOUSING ASBLY RCLNR 9153641541
WHEELCHAIR PARTS	8881127476	KIT BACK UPH 18WX16H W/HDWR VY
WHEELCHAIR PARTS	8881091728	SEAT UPH 22WX18D