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William N. Parham III
Director, Paperwork Reduction Staff
Office of Strategic, Operations, and Regulatory Affairs
Division of Regulations Development
Centers for Medicare and Medicaid Services
Attention: Document Identifier/OMB Control Number 10861
Room C4-26-C05
7500 Security Blvd.
Baltimore, MD 21244-1850

Submitted electronically to <http://www.regulations.gov>

Attention: Document Identifiers: CMS–10861

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Dear Mr. Parham,

The Los Angeles-based **AIDS Healthcare Foundation (AHF)** appreciates this opportunity to comment on **CMS–10861**. AHF is a nonprofit organization providing cutting-edge medicine and advocacy to millions of people in 45 countries. We are currently the largest provider of HIV/AIDS medical care in the U.S. AHF funds its mission to rid the world of AIDS through a network of pharmacies, thrift stores, healthcare contracts, and other strategic partnerships. Generating new, innovative ways of treatment, prevention and advocacy have been the hallmark of our success. One of our innovative ways to identify HIV/AIDS is by providing private and convenient community based locations including mobile units for testing. Innovative treatments include interdisciplinary care coordination with whatever level of privacy desired by the client, focusing on medication adherence to achieve undetectable viral load. Currently, AHF has a Medicare C-SNP in California and Florida specifically designed for HIV beneficiaries and was, in fact, the first to establish such a C-SNP.

COMMENTS

We have reviewed the CMS memorandum and Supporting Statements pertaining to changes and field testing of the Health Outcomes Survey (HOS) instrument. Our comments are based on all of the years of experience we have with work with the HOS and our beneficiaries in addition to

discussions with the SNP Alliance. We may be re-iterating comments made by SNP Alliance to demonstrate how strongly we support them. We strongly support the addition of a web-based mode for collection.

Concerns related to the proposed field testing methodology are as follows:

- ***Further revisions to the Instrument*** - HOS instrument needs a more major overhaul and the methods of measurement and reporting utilizing HOS in the Medicare Advantage quality measurement program likewise need substantial changes in order for this to be used in a way that is fair, equitable, and appropriate and to generate accurate and reliable results to guide improvement. Conducting a field test of a few items and the response rate from a web-based survey mode versus the traditional way of collecting HOS data is not a good use of resources given the other limitations of HOS.
- ***Attention to Proposed Analysis & Use*** –HOS is not an adequate measurement tool to be used as the vehicle for performance evaluation of a plan nor for comparisons across plans for the longitudinal measures which currently are based on HOS.
- ***Field Testing Modifications*** - Field testing is an important step—but only as part of an effort to ensure that the HOS instrument is valid and reliable for all sub-group populations in which it is intended to be used. Unfortunately, there is strong evidence that this is not the case. The HOS instrument (all questions) needs to be part of a field-testing effort, not only the proposed new items.
- ***Inaccurate Cost Estimates*** – To be useable by the Medicare program and all stakeholders, and to support articulated health equity goals, revisions to HOS and field testing must be more substantive. Even as outlined in the PRA Notice, the cost estimates are substantially under-estimated.

RECOMMENDATIONS

Recommendation #1 – OBTAIN SUBSTANTIVE INPUT FROM AFFECTED STAKEHOLDERS AS PART OF MORE SUBSTANTIAL REVISIONS TO HOS - The HOS instrument needs more substantial revisions than are being proposed if it is to be used in a fair and equitable quality measurement and reporting system. The whole instrument needs additional review with more stakeholder input from diverse communities for comprehension, format, accuracy, validity, and utility. The proposed revisions are insufficient to address the issues raised in the past such as current disability status, prognosis, health equity, cultural competency, etc.,

- *Social Risk Screening* Items #42 through #53 – We do not recommend adding these items to the Health Outcomes Survey—as these same social risk issues of housing, food, transportation insecurity already have been added to required social risk screening through the Health Risk Assessment. CMS has already indicated the validated and

standardized risk screening survey items that are acceptable for use in the HRA. Likewise, the NCQA already has a measure for social risk screening and follow-up that focuses on these same three risk issues. This NCQA measure is on the pathway to be used in the Medicare Advantage quality measurement system by CMS, as indicated in proposed rulemaking. Finally, the wording of the social needs items based on online interviews with “9 or fewer respondents” is not an acceptable basis for developing a survey item. The items, if added, must be based on validated items where the wording and response options have been tested, such as in the PRAPARE or AHC tools. Furthermore, since the HOS data is blinded to the health plan and also not available to the provider or support services professionals working with the beneficiary, the addition of these questions could cause confusion within the individual—thinking that by responding to this survey they have now indicated need which will be reviewed and addressed by their health plan or doctor. We recommend focusing on the Health Risk Assessment requirement and quality measures already in play that address social risk screening and follow-up.

In summary, the social risk items are redundant and represent an unnecessary burden on the individual. Including these items in HOS will not provide information to guide response to the person and could cause harm to the individuals who do have vulnerabilities in these areas and might believe or assume that filling out this survey equates with notification of need for help where someone will be responding.

Regarding the items being DELETED, we have the following comments and recommendations for adding items back in:

- *LIVES ALONE* - The item that was in HOS regarding whether the person “lives alone or with others” should NOT be removed. This is an important characteristic, especially given substantial research and practice evidence of an increasing rate of social isolation and lack of family/care partner support among older adults and those with physical disabilities. In addition, a brief published by Rand research in year 2000 indicates 10% of children under 2, live with grandparents. This means a Medicare recipient is a caretaker for the child and may contribute to the beneficiaries health and well-being.
58. Do you live alone or with others? (One or more categories may be selected)

1 ☐ Alone

2 ☐ With spouse/significant other

3 ☐ With children/other relatives

4 ☐ With non-relatives

5 ☐ With paid caregiver
- *CONDITIONS* – The items where the individual indicates their conditions where “a doctor has told you that you had . . .” and “are you currently under treatment for” should

be added back in. These questions build the profile of the person which contributes to understanding their level of complexity.

- *PROXY Response* – We strongly recommend that the item indicating if the person had a proxy respondent be added back. This is extremely important for understanding and comparing responses and it is standard practice to separate proxy respondents from self-directed responses. This is particularly important if the respondent was a paid professional caregiver. We do not understand why this was removed.

61. Who completed this survey form?

- ☐ 1. Person to whom survey was addressed → **STOP HERE**
- ☐ 2. Family member or relative of person to whom the survey was addressed → **Go to Question 62**
- ☐ 3. Friend of person to whom the survey was addressed → **Go to Question 62**
- ☐ 4. Professional caregiver of person to whom the survey was addressed → **Go to Question 62**

Recommendation #2 – CONSIDER UTILITY OF THE DATA - HOS Data Insufficient for Comparison and Improvement - HOS does not support performance evaluation nor comparison across plans and does not provide information to guide quality improvement.

- *Blinded Respondent Sample Does Not Offer Actionable Information* - Unfortunately, blinded longitudinal data does not offer information that is actionable to a health plan or provider. It would be useful for an individual to discuss their self-report of status, compared to his/her/their self-report of status two years ago, with their provider as part of care conversations—but that is not how HOS is used. Providers are unaware and unable to see who or how their patients have responded to status questions.
- *Biased Sample* - The composition of the respondent pool is inadequate to support the goals of equity, accuracy, and utility. Even if the response rate improves with the use of web-based surveying methods, the respondent sample is heavily biased to White, English-speaking individuals.

Recommendation #3 – TEST THE WHOLE INSTRUMENT, NOT PIECES/ITEMS SEPARATELY - A true test of a survey instrument involves the question order, format, length, and total duration to complete--not just each individual item posed separately. Response rate is important, but comprehension of each item and the instrument as a whole, in the way that it is experienced by the respondent, is at least equally important. The response scales may not be equally understood by different sub-population groups. Examining the survey as a whole and the response scale comprehension among diverse population sub-groups should be included in the field testing—especially if CMS wishes to compare two versions of a revised instrument and wishes to understand how comprehension and response may differ based on characteristics of the person completing the survey.

Recommendation #4 – ATTEND TO CONTRACT SELECTION TO ACHIEVE A DIVERSE FIELD-TESTING SAMPLE – When ready HOS is for field testing, we strongly advise attention

to selecting contracts that include a high proportion of diverse beneficiaries, for example where over 80% of enrollment is dually eligible, disabled or low-income, and where contracts have a substantial enrollment of non-White, non-English speaking individuals. We also recommend selecting a set of contracts that predominately serve frail elderly, and a set of contracts that predominately serve persons with high behavioral health needs and physical disabilities.

Recommendation #5 – SUBSTANTIALLY INCREASE/IMPROVE THE SAMPLE SIZE and COMPOSITION – The sample size and composition for this proposed field test are not adequate. As noted, we recommend that the sample size be substantially increased and diversified through purposeful selection of contracts with high proportion of dually eligible, diverse, and complex individuals. This would allow for oversampling among certain groups--to ensure that persons of color, non-English-speaking persons, and individuals with condition complexity and social risk characteristics are sufficiently represented in this field testing to allow for sub-group analysis.

Recommendation #6 – CONDUCT SUB-GROUP ANALYSIS – The Health Outcome Survey must be adequately tested in non-White and non-English speaking individuals and those with low literacy to ensure that the questions and scaled responses are understood and meaningful to these individuals. It is critical to conduct analysis of individuals who are non-White, dually eligible (a proxy for high social risk), and non-English speaking and compare them to individuals who do not have these characteristics. Sub-group analyses must be done. This will inform how/when/if to use HOS with these population. This can be part of a larger effort around HOS to determine if diversity characteristics impact HOS responses. This will be an important step to examine accuracy, validity, feasibility, and utility issues in groups who have a different racial, ethnic, language, literacy, and economic profile than the Veteran population upon which HOS was developed. Proper inclusion of diverse populations in all aspects of development and testing is in keeping with the health equity goals espoused by CMS, HHS, and this Administration.

Recommendation #7 – FULL TRANSPARENCY ON RESULTS – Researchers and CMS must fully report results from qualitative and quantitative examination of HOS and from this field testing. This information is vital to inform future directions for many stakeholders and will be useful beyond the initial purpose of modifying one instrument. The information should be distributed as soon as possible after analysis in keeping with transparency and accountability standards held by the U.S. government.

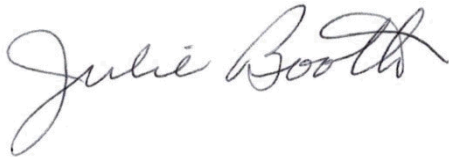
Recommendation #8 - RECALCULATE BURDEN AND COSTS – The Supporting Statement A indicated expected burden and costs via the hours and wages for conducting the survey once with an estimate of the average time to complete the HOS as 15 minutes at \$28.01 per hour and the only costs included are those of the respondent.

Time to complete HOS is underestimated. We do not agree with the time of 15 minutes, particularly if the respondent completes the full HOS (as recommended) to provide CMS with a much more complete picture of response to the questions on HOS (not only the new ones proposed) ensuring that respondent differences by key characteristics (e.g., race, dual status, primary language) are captured and analyzed. A closer estimate of time would be 60-75 minutes per respondent.

Costs borne by others not shown – The costs to administer the survey, presumably utilizing approved survey vendors that meet the training requirements set by CMS, are not included in the PRA Notice. This will be important for estimating costs to health plans in the future as the health plan must cover the cost of HOS annual surveying of its members. This is pertinent to determining not only the field testing cost, but the burden going forward—and is in keeping with the intent of the Paperwork Reduction Act.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "Julie Booth". The signature is written in dark ink and is positioned below the word "Sincerely,".

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