

HRSA Response to OMB Comments on Patient Navigator Program

Thank you for your careful reading of the Supporting Statement document. We have made revisions in the two documents as suggested. Our changes are highlighted in blue, and OMB changes remain highlighted in yellow.

In addition, below please find our responses (in bold blue type) to your specific comments (in italics):

1. *Please see attached for suggested edits to Part A (there is also a suggestion about moving something from Part A to Part B). Most of the suggested edits have to do with clarifying that the clinical outcomes component is designed to look at “Short term changes in intermediate clinical outcomes specific to the primary navigated condition for those patients that accessed appropriate care.”*

If possible, we would prefer to use the term “intermediate health outcomes”. The intermediate health outcomes are:

- Patient-reported health status using the VR-12
- Clinical information (including clinical status and risk factors)

We agree that the evaluation is measuring “short-term changes” on these outcomes; ideally these outcomes should be monitored over the long term for patients with chronic disease. We have made changes accordingly in Section A. We also moved several paragraphs from Section A to Section B, and all these changes are highlighted in blue.

2. *Please provide the final versions of the instruments because many of them say “draft do not use this version”*

The final documents are attached.

Question -- how does HRSA intend to maintain quality control among sites, given the following language that appears on many of the instruments:

“Using the Navigator Characteristics Form. You are welcome to customize and otherwise modify the formatting of the Navigator Form. For example, you may choose to highlight options under required elements (categories) applicable to your site, or to delete those that are not applicable. However, you are responsible for the information on the form, so take care to avoid deleting required data elements. Since the data entry screen on the online database will mirror this data entry form, major changes are likely to cause increased data entry effort. If there is doubt about whether a specific modification may cause problems, please contact NOVA.”

The concern is that because HRSA is not signing off on the modifications, you might not know that inappropriate changes that affect data quality have been made until after the fact. Please consider some sort of sign off for making changes.

It seems simplest to require that the grantees use the forms as they are, without modification, and we will communicate this to them.