APPENDIX F

SOFTWARE GUIDELINES

1. PURPOSE OF GUIDELINES

This document is intended for use by developers, vendors, and consumers of software intended to provide home care agencies with the capability of electronically encoding OASIS data for the purposes of patient assessment and outcome measurement. It is not a statement of official CMS policy, except to the extent that the guidelines reflect requirements that are or will be imposed by regulation. The primary purpose of the guidelines is to assist home care agencies in making choices that will ensure accurate, consistent, and useful OASIS data.

The guidelines in this document apply to three different types of software. The first is point of service clinical documentation software, typically used in the home by clinical staff responsible for assessment and care provision. Such software ordinarily replaces pen and paper documentation, and may be implemented using laptop, pen-based, or hand-held computers. The second type of software is data entry and tracking software used by a home health agency, typically in the office rather than in the home. Optical scanning represents a third automation option which is essentially similar to data entry software in the function it serves. The special considerations that apply to scanning systems are described in the data entry systems section of this document.

CMS makes data entry software (HAVEN) available to home health agencies at no charge. HAVEN provides the following functions: data entry of OASIS data from paper forms, validation of data records according to CMS specifications, data export according to CMS' specified format for OASIS data, and basic data management and reporting. Agencies may elect to use HAVEN or any other product that meets CMS specifications for OASIS data reporting.

This document does not cover technical requirements for OASIS data submission, electronic record formats, or data accuracy and edit checks, nor is there any discussion of CMS requirements regarding timing of data entry, locking and data submission. These topics are dealt with in other documents, including the OASIS Data Submission Specifications published on the CMS OASIS web site, the OASIS Home Health Agency System User's Guide, and the HAVEN Reference Manual.

2. GUIDELINES FOR POINT OF SERVICE CLINICAL DOCUMENTATION SOFTWARE

The expectations for incorporating the OASIS into clinical documentation software to be used by clinical staff in the field are as follows:

a. All applicable OASIS items must be included in the clinical documentation software for each required assessment. The text of OASIS clinical assessment items as they appear on screen must be worded exactly like the OASIS items as published. The CMS regulation regarding comprehensive assessment specifically states that OASIS items must be incorporated into the agency's assessment with exact wording. This requirement applies to electronic assessment forms in the same way it applies to paper forms. The following exceptions are permitted:

- Identifying information and basic demographic data, such as patient name, Social Security number, Medicare or Medicaid number, year of birth, and gender can be copied from another source the agency uses to collect this information, as long as the format and coding of these items conform to the corresponding OASIS items.

- Some OASIS items include a response of "Other (specify)_____." Agencies or software vendors will probably find it useful to have a means of entering text in response to the "(specify)" instruction, but this is optional. The text information is not included in the OASIS data set that will be electronically reported, although the selection of "other" as a response is to be encoded.

b. It is understood that some clinical documentation software will have limitations in the amount of text that can be displayed on a single screen or in a particular display field. Therefore, scrolling is acceptable, or the full text of an item may be accessed by a "pop-up" screen that appears only when that particular item is encountered. However, the display of the full text should not be optional, and should not require any special action by the user, such as pressing a function key. Whenever a response is expected to a particular OASIS item, the entire text of the item should be displayed.

c. When OASIS items include text that is emphasized by underlining or bold face, the point of service clinical documentation product should reproduce this emphasis in some way. If bold and underlined text cannot be displayed, emphasis may be indicated by capitalization or font color.

d. Skip patterns should be carefully observed and incorporated into the software. For example, the OASIS includes a series of questions on wounds.

If the patient has no wound or skin lesion, the first question in the series directs the clinician to "skip" the subsequent wound items and go directly to the next appropriate item in the record. It is recommended that this skip pattern be built into the software so that it is automatic.

e. For follow-up or discharge assessments, data (other than patient identifiers and demographic information which remains constant) should not be carried forward from an earlier assessment. The assessment should be done without reference to previous values of any data item. It is vital to assuring that a valid assessment is completed that the care provider collecting data at follow-up or discharge time points not be allowed to duplicate data values from prior time points as a default option.

f. OASIS items should be integrated into the standard product, not presented as a separate module or section. This means that OASIS items should be interwoven with other assessment items that are part of the clinical record. If, prior to integration of OASIS items, the software included items similar to those in the OASIS, the OASIS item should replace the original assessment item. The OASIS items may appear in any order that fits with the structure of the clinical documentation system.

g. Data edit checks should be incorporated. Checks for complete data for all required items as well as basic checks for logical consistency should be included. It is recommended that edit checks be implemented within the software clinical staff use in the patients' homes, so that problems are noted during or immediately upon completion of the assessment. If this is not feasible, a separate software module may be used to check the data (soon) after the assessment is completed. When data are submitted to a CMS-designated State agency in compliance with the data reporting regulations, each record will be expected to meet the completeness, range, format, and consistency criteria included in the OASIS Data Submission Specifications. Therefore, it is to an agency's distinct advantage to subject data to these edit checks prior to submission.

h. Software must provide a means for locking records and date stamping in compliance with regulations, and for exporting data in the standard CMS-specified format (including masking specifications, if applicable) for submission to the State agency designated by CMS.

i. Software must provide for correction of data entry or other errors, in keeping with current specifications as published by CMS.

3. GUIDELINES FOR DATA ENTRY SOFTWARE

The following guidelines apply to software used for data entry of pen and paper assessment forms. Some of these guidelines are the same as those for point of service clinical documentation.

a. All forms of OASIS assessment should be accommodated. These include assessments at the following time points: start of care, follow-up at 60-day intervals, discharge, transfer to inpatient facility, and resumption of care following an inpatient stay. The software should include the appropriate OASIS items for each specific type of assessment. Unlike point of service products, it is not necessary to display the full text of each OASIS item, because the OASIS text will appear in the paper clinical documentation forms. However, it would facilitate review of data to display the full text of each OASIS item.

b. Some OASIS items have changes in response items, between the start of care assessment, follow-up assessments, and discharge assessment. For example, "unknown" responses are included for some items at start of care but not at follow-up or discharge. The software must present the appropriate responses for each item consistent with each specific type of assessment. Appendix D of this manual includes checklists for making sure that the appropriate item differences are maintained.

c. Data edit checks should be incorporated. Checks for complete data for all required items as well as basic checks for logical consistency should be included. It is recommended that edit checks be implemented during or immediately upon completion of data entry of an assessment, so that data entry errors can be corrected immediately, and discrepancies in the assessment can be resolved with the clinician responsible for the assessment in a timely manner. If this is not feasible a separate software module may be used to check the data (soon) after data entry is completed. When data are submitted to a CMS-designated State agency in compliance with the data reporting regulations, each record will be expected to meet the completeness, range, format, and consistency criteria included in the OASIS Data Submission Specifications. Therefore, it is to an agency's distinct advantage to subject data to these edit checks prior to submission.

d. For follow-up and discharge assessments, data (other than patient identifiers and demographic information which remain constant) should not be carried forward from an earlier assessment. Data entry should be done from hard copy without reference to previous values of any data item.

e. Software must provide a means for locking records and date stamping in compliance with regulations, and for exporting data in the standard CMS-specified format (including masking specifications, if applicable) for submission to the State agency designated by CMS.

f. Software must provide for correction of data entry or other errors, in keeping with current specifications as published by CMS.

4. GUIDELINES FOR OPTICAL SCANNING SYSTEMS

The following guidelines apply to software used for processing of optical scanning assessment forms. Some of these guidelines are the same as those for point of service clinical documentation and data entry products. When an optical scanning system is used, the paper form completed by the clinician is an integral part of the data capture system. The forms should conform to the integration guidelines presented in Chapter 7 of this manual. The following guidelines are predicated upon the assumption that the forms are appropriately designed and the scanning hardware/software combination works, in the sense that what is marked on the form is accurately captured and encoded into a database.

a. Data edit checks should be incorporated. Checks for complete data for all required items as well as basic checks for logical consistency should be included. It is recommended that edit checks be implemented immediately upon completion of scanning of an assessment, so that scanning errors can be corrected immediately, and discrepancies in the assessment can be resolved with the clinician responsible for the assessment in a timely manner. If this is not feasible, a separate software module may be used to check the data (soon) after scanning is completed. When data are submitted to a CMS-designated State agency in compliance with the data reporting regulations, each record will be expected to meet the completeness, range, format, and consistency criteria included in the OASIS Data Submission Specifications. Therefore, it is to an agency's distinct advantage to subject data to these edit checks prior to submission.

b. Software must provide a means for locking records and date stamping in compliance with regulations, and for exporting data in the standard CMS-specified format (including masking specifications, if applicable) for submission to the State agency designated by CMS.

c. Software must provide for correction of data entry or other errors, in keeping with current specifications as published by CMS.

5. GUIDELINES FOR DATA TRACKING SYSTEMS

Certain tracking features should be incorporated into any OASIS data system, regardless of the method of data capture. To the extent that data tracking is automatic, considerable staff time can be saved and data quality is likely to be enhanced.

a. An agency should be able to track its own compliance with comprehensive assessment requirements, specifically the following:

- Have the required assessments been completed? What assessments are missing?
- Have assessments been completed on time? Which assessments are not timely?
- Is data entry, editing, and locking occurring in a timely manner?
- What is the extent of data quality problems (missing or inconsistent data), and are they resolved in a timely manner?

b. Tracking software should verify key patient identifier information for new assessments against previous assessments (and, if part of an integrated system, against a master patient record) and issue warnings of nonmatches or of an attempt to add follow-up or discharge assessments for a patient who is not in the database.

c. It is recommended that software also enforce record sequencing, i.e., the user should be warned when an attempt is made to add an assessment record that is out of logical sequence compared with the most recent assessment data for the same patient. (Example: Resumption of Care assessment completed following a Start of Care assessment, with no intervening transfer to inpatient facility.)

d. It is recommended that reminders be generated by tracking software. Periodic lists of patients on service that are coming due for follow-up assessments are very useful.

Many of the tracking features listed above can be and are built into data entry, point of service, or scanning systems, or can be added on at relatively little cost and effort. For example, generation of reports often is an integral part of the data entry system. If report generation is not built into the system, but the data entry system uses a standard database format for storage of OASIS data, an agency may be able to produce the reports it needs using off-the-shelf database software that does not require a high level of programming expertise.

6. EVALUATING SOFTWARE

The minimum criterion for evaluating software that will be used for the purpose of encoding OASIS data should be that it enables your home health agency to comply with the CMS data reporting requirements. CMS does not test software products or maintain any kind of approval or certification system for software vendors. It is up to each individual home care agency to determine whether a product complies with CMS requirements.

The data validation feature built into HAVEN provides a tool which can be used to evaluate other software. In addition to providing a data entry system, HAVEN also incorporates a data import facility which includes data validation. One way to test if a software product's edit check and data export features comply with CMS specifications would be to attempt to import the data into HAVEN. HAVEN will apply the same validation checks to imported data as it uses to validate data that is keyed into HAVEN. The user also has the option of applying validation checks as a pre-import step, without actually importing records into the HAVEN database.

A second means of determining if an OASIS data capture product meets CMS specifications is to generate a test batch of data for submission to the State OASIS system in your State. When a test data batch is submitted, the State will also apply the validation checks included in the Data Submission Specifications. Records which do not meet range checks or which have missing data are rejected.[1] Therefore, it will be advantageous to ensure that your agency's data meet the data specifications in all respects to avoid the possibility that records will be rejected.

Testing whether a data export file produced by a particular software product meets the CMS format and validation specifications is a necessary step, but numerous additional criteria, such as those listed previously in this appendix and in Chapter 10 of this manual, must be applied to determine what approach and which products will best meet your agency's needs.

[1] Note that HAVEN enforces missing data and range checks, by preventing the entry of out-of-range values and preventing export of records with missing or inconsistent data. The State enforces the same criteria as HAVEN, rejecting records with missing, out of range, or inconsistent data. Certain discrepancies, usually pertaining to date inconsistencies that indicate untimely assessments or untimely data entry and locking, generate a warning message without causing rejection of the record. In this respect, the State system and HAVEN mirror one another.