September 21, 2007

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development-C
Attn: Bonnie L. Harkless
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: 72 FR 41328

The American Health Information Management Association (AHIMA) welcomes the opportunity to comment on the US Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) Data Collection for Administering the Medicare Continuity Assessment Record and Evaluation (CARE) Instrument.

AHIMA is a not-for-profit professional association representing more than 51,000 health information management (HIM) professionals who work throughout the healthcare industry. AHIMA's HIM professionals are educated, trained, and certified to serve the healthcare industry and the public by collecting, managing, analyzing, reporting, and utilizing data which is vital for patient care, while making it accessible to healthcare providers and appropriate researchers when it is needed most.

AHIMA and its members participate in a variety of projects with other industry groups and federal agencies related to the use of healthcare data for a variety of purposes including direct care, quality measurement, reimbursement, public health, patient safety, biosurveillance, and research.

AHIMA commends CMS for carefully gathering and assessing input from industry stakeholders during the development of the CARE Instrument. Our comments focus on those areas of particular interest to our members and we believe we have provided a thorough and comprehensive response to the instrument which serves as a good foundation from which to begin standardization efforts; however, we have outlined some recommendations for consideration as CMS continues to refine the assessment instrument.

We would be happy to assist CMS with making any changes or modifications to the CARE Instrument. AHIMA has a history of strongly supporting many of CMS' initiatives and providing our expertise in domains that reflect that knowledge area. We would look forward to collaborating on this important effort to ensure facilities experience the most efficient and effective data collection methodologies.

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General Comments

a. What will be required when an acute care facility sends a patient *home*, but then decides on a visiting nurse services (VNS) within three days? Will facilities be required to query the CMS database to check, and if so, will the facility staff be required to fill out the form? AHIMA recommends that CMS provide additional information regarding this process.

b. If the patient is discharged to a setting that is not Medicare-certified or is covered under Medicare, is the CARE Instrument still required to be filled out?

c. What is the time frame for the form to be completed once a patient is determined to meet admission criteria for home health (HH)? If a patient is discharged home from an acute care setting with no HH services and the physician determines after three to four days that the patient requires HH services, how will the data be ascertained from the facility that has already discharged the patient? AHIMA recommends providing additional clarification on which entity/facility is responsible for completing the form.

d. While discharge planning may need Other Services (Skilled Nursing Facility (SNF) or VNS), sometimes the patients do not respond to the recommended follow-up services. Facilities anticipate filling out the CARE Instrument and envision acute care facilities doing a lot of "what if" work, just to be potentially compliant.

e. There is some concern over the use of the terminology for a Long Term Care (LTC) facility versus a Long Term Acute Care Hospital (LTCAH). There are some who believe that an LTC is the same as a SNF. What would be considered the difference between a LTC hospital and LTCAH? AHIMA recommends that CMS clarify the terms and classifications being used to describe specific medical settings. The terms can mean different concepts to different users of the CARE Instrument.

f. There are operational issues associated with completing the coding of a patient's chart prior to their discharge. This will affect coders who have transitioned to a telecommuting opportunity which allows them to code from home. AHIMA is concerned about the impact on the resources and recommends that CMS consider the operational issues associated with implementing such a instrument and allow an opportunity to vet out these issues during the demonstration project. Many facilities around the country have transitioned or recently transitioned to home coders and thus, requiring coders to return to the facility environment will have an impact on all resources associated with this process.

g. What are the expectations from CMS on the completion of the CARE Instrument? Is the expectation that the instrument be completed when a patient moves from one post acute care setting to another? For example, moving from home to a SNF. AHIMA recommends that CMS clarify the process as to when and/or at what stage this form must be completed.

h. The form is incredibly complex and interdisciplinary. The amount of time and number of hours, number of personnel involved in its completion, and the complexity of the information required is enormous. CMS should consider if this information is of value and actually useful, or if this is just an exercise in data collection. It is very easy to collect data, but it is of no value if it is not used or not useful. Other than information to be transferred to the PAC setting, what does CMS anticipate using the data for? What secondary data uses are expected? AHIMA recommends CMS further clarify the anticipated purpose of the data being collected.

i. Information from a patient's chart is often not complete during the admission process to a facility. Entries are typically made throughout the course of a patient's stay and are completed post discharge to ensure a complete record. AHIMA recommends CMS consider the length and enormous data collection requirements necessary to complete this instrument.

j. The CARE Instrument will be very burdensome, especially for acute care, unless there is a planned way to export data from a hospital information system. Discharge planners, social workers, and nurses have a large amount of paperwork to complete to prepare a patient for discharge or transfer without the additional burden of a 20-page instrument required for post acute care. The health information technology (HIT) environment is currently in a transition period, thus collecting data from hybrid systems is certainly a challenge.

k. While admission criteria for IRFs and SNFs exist, there are no admission criteria for the other settings. Trying to "standardize" these care settings through a data collection instrument will be very difficult, given CMS's own standards on appropriate levels of care. A stroke patient who might be appropriate for home health would most likely not be appropriate for IRF or SNF care and vice versa. Currently, the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) is designed to help demonstrate why the patient meets IRF admission criteria.

l. IRFs have a long partnership with Functional Independence Measure (FIM) scoring and decades of comparative outcomes data based on FIM scoring. To continue using that historical data, does CMS propose that IRFs continue to participate with UDS or E-Rehab as well as having to complete this new instrument? If the hope is that IRFs could get their comparative data from the CARE Instrument, then is there a data mapping tool planned so historical data is not useless? AHIMA recommends CMS provide additional guidance or information for this element.

m. CMS has provided screen shots of an electronic version of the CARE Instrument. Will a PAC provider have the option to look patients up via their Medicare number, social security number, or other identification number to identify what other settings the patient has been in? Will this information be stored in a timely manner so that the most current information is captured for retrieval?

n. According to the directions in the instrument, providers are being required to sign/certify the CARE Instrument. AHIMA is unsure whether the CARE Instrument should be a part of the legal record. We recommend CMS provide additional guidance or information.

o. It is not clear which sections are required to be completed and by which discipline. AHIMA recommends allowing for an initial or signature for each section to demonstrate completion of the sections.

p. If manually completing the instrument, the boxes in which codes are entered in a separate shaded area next to the text and may confuse the user of the instrument. AHIMA recommends that the box appear right beside the text to make it very clear what information should be entered into each box.

q. Signature Section–CMS has provided screen shots of an electronic version of the CARE Instrument. AHIMA requests clarification on whether this instrument will use electronic signatures. If so, it is unclear who will maintain each person's unique signature "codes" or "PINs."

r. Although CMS may only require PACs to submit just one form, eventually, facilities may choose to continue using their individual data collection mechanisms to fit their needs. This would increase the data collection burdens for the facilities. By completing the CARE Instrument, it creates additional work for the facilities. With current initiatives underway led by the Secretary of HHS to conduct data standardization and promote HIT AHIMA recommends considering the other data reporting requirements that are called upon by the facilities to complete.

s. It is unclear how the CARE Instrument assists in collecting the necessary data for ORYX, which is required by the Joint Commission. Currently data can be pulled from the OASIS which eliminates the need and burden of collecting additional data.

t. Patient education is needed to explain why this data is being captured. AHIMA recommends CMS develop a patient education and awareness program.

u. AHIMA recommends that CMS add to the current notice of privacy practice (NPP) or create a separate form to let the patient know this information is being captured.

I. Administrative Items

a. **A. Assessment type**–It is unclear whether this instrument is required to be completed in its entirety at admission and discharge, or if only certain parts need to be completed twice.

- It is unclear what the term "Interim" assessment means. Why would someone perform an assessment on someone who is expired? Expired is a discharge disposition. AHIMA recommends that CMS further clarify the terms used for "Reason for Assessment".

b. **B. Provider Information**–It is unclear whether the information being requested in this section is an institutional provider or an individual provider. AHIMA recommends CMS provider further clarification to ensure accurate data is captured in this section.

c. **C.10 Gender**–AHIMA recommends that CMS reconsider only offering two gender types as a patient may present as a transsexual, or one with chromosomal abnormalities which may be undetected. We recommend adding another option for Other.

d. **C.11 Race/Ethnicity**–Information requested in this category is often not included in a patient's records. Some admission departments are hesitant to ask and have instructed their staff to make a guess about the patient's race/ethnicity. Some facilities assume that a Hispanic surname makes the patient Hispanic. This is not always true as it could be a woman's married name, and have nothing to do with her ethnicity.

   Also, many people, including Hispanics, think that Hispanic/Latino are a race, not an ethnicity. The US Census Bureau asks for race first, and THEN ethnicity. AHIMA recommends that CMS should consider following the Census Bureau's process of collecting data on the Race/Ethnicity category.

e. **C.12–C.12b English as Primary Language**–After establishing whether or not English is the patient's primary language, C12a asks if an interpreter is available. (0 – No, 1 – Yes) While English may not be the primary language, the patient may still be conversant in English. AHIMA recommends adding "N/A" as a third option rather than requiring a No/Yes response.

f. **C.13a–b Advance Care Directive**

- Both questions A & B refer to Advance Directives (ADs) and ADs are only for patients age 18 or older. Since there is the potential that the CARE Instrument could be completed on a patient who is under age 18, AHIMA recommends offering an additional choice that indicates the patient is under the minimum age for completing an AD.

- C13b–Indicates if the record documents who has authority to make decisions if the patient is unable. Each state has its own AD laws, and they can vary significantly, especially as it relates to activation of the AD. It is important that the assessment instrument also request information if the AD has been activated. (In some states, the AD is NOT valid unless it has been activated.)

II. Admission Information

a. **A.2.1–A.2.2 Admitted From**–There is confusion regarding the response to this question, (i.e. "long term nursing facility in A2.1 and SNF in A2.2). The data would be inconsistent even if facilities were further defined. AHIMA recommends that CMS provide further clarification on the terms listed.

b. **A.3–A.3.a Admission from a medical setting/ last primary diagnosis**–In most, if not all inpatient settings, the term *principal diagnosis* takes precedent over *primary diagnosis*. Sometimes the primary diagnosis in an acute care setting is not the same as the primary diagnosis in the PAC setting. What is the definition for primary diagnosis? AHIMA recommends that CMS provide a definition for further clarification and to assess the need for consistent reporting.

c. **A.3 Setting**–Does "medical setting" mean anything except home? Will the facility completing this instrument be expected to call and get this information? AHIMA recommends that CMS provide further clarification on this section.

d. **A.4 Other medical services**–Will the facility completing this instrument be required to call around the community to determine if the patient has received care in these various settings if the patient or family doesn't remember? AHIMA anticipates that this process will be very time consuming to the facility, including completing the form itself. We recommend that CMS provide further clarification on the expectation of this section and would recommend that CMS add another choice: j. unknown (or unable to obtain).

e. **A.4 Other medical services**–Currently, many HH facilities are not timely in submitting their Request for Anticipated Payment (RAP), which does not allow another admitting facility any information in the CWF (Common Working File). This will potentially create a situation of increased agency over-laps, transfer disputes and lost revenue for HH agencies.

f. **A.2 and 4 Short stay acute hospital**–The phrase "Short-Stay Acute Hospital" is confusing and might be confused with an observation stay only versus an individual who was in acute care hospital for two months prior to being transferred to PAC facility. AHIMA recommends CMS provide further clarification.

g. **A.2, B.1, and B.3 Reach back information**–The data being collected in these sections appears conflicted. For B.1., AHIMA recommends that CMS describe how far back the data collector is supposed to look before the information becomes irrelevant.

h. **B.1 Prior to this recent illness, where did the patient live?**–AHIMA recommends removing the term "permanent" from "long term care facility/nursing home" as the patient could transfer from a nursing home after a short-stay. Or perhaps include instructions that a transfer from a short-term nursing home stay would be coded as "other".

i. **B.5 Prior Functioning**–Concern has been expressed over another scoring metric that is not FIM-based. AHIMA suggests that CMS consider using a standard data capture methodology for this category.

j. **B.8 Prior Mental Status**–Capturing this information may be difficult to document in the CARE Instrument and also patient may not be asked this question due to various conditions.

III. Current Medical Items

a. **A. Primary Diagnosis**–What is the definition for primary diagnosis? A definition is needed for consistent reporting and maintaining data quality/integrity.

- OASIS currently has a very specific definition, the primary diagnosis is the condition most related to the current plan of care.
- The IRF-PAI doesn't use primary diagnosis; it uses etiologic diagnosis which has a very different definition.
- The Uniform Hospital Discharge Data Set (UHDDS) uses the term "principal diagnosis." This is the name of the data element on the UB claim form; it would result in more standardization, and less confusion, if "principal diagnosis" was used on the PAC instrument instead of "primary diagnosis." With the current post-acute data sets, there is a great deal of confusion with the use of different terms and definitions principal diagnosis, primary diagnosis, and etiologic diagnosis.

b. **A.2.a If primary diagnosis was a V code, what was the primary medical condition or injury being treated?**–AHIMA is not sure what this question means. Is this supposed to capture the underlying reason (or etiologic diagnosis, as it's called on the IRF-PAI when the underlying diagnosis impacts the payment group, it is called a case mix diagnosis on OASIS) for the PAC? We recommend that the question be reworded for clarification. For example, in post-acute care, the patient may be receiving aftercare following a surgery for a condition that the surgery resolved. The diagnosis necessitating the surgery is not being "treated" in the post-acute setting.

c. **B. Other Diagnoses, Comorbidities, and Complications**–AHIMA recommends providing a definition of what this is intended to include. For example, OASIS defines other (secondary) diagnoses as all conditions that coexisted at the time the plan of care was established, or which developed subsequently, or affect the treatment or care. The IRF-PAI also has a specific definition for comorbidities and complications.

- It is unclear what "include under-reported diagnoses" mean? Are coders expected to code according to Official Coding Guidelines and UHDDS definitions? If those conditions listed as examples are being treated, evaluated, or monitored, should they not be coded? AHIMA requests that CMS provide further clarification.
- Is this section expected to be complete upon discharge? Conditions can and do get diagnosed during a PAC stay. AHIMA requests further clarification on where these issues would get reported as they can change the discharge disposition.
- It is unclear why the diagnosis needs to be written out. Is the reporting of the code sufficient? AHIMA requests clarification as to the purpose for including the diagnosis description.
- AHIMA is concerned that the allowable space for the number of codes may not be sufficient for a patient transferring to a PAC setting. We recommend CMS provide additional lines for adding codes.

- Coding should be conducted by an experienced and trained professional coder. AHIMA is concerned regarding the quality and integrity of the data being entered.
- AHIMA is concerned regarding the handling of coding changes and the impact it will have on the web based software used for the assessment. AHIMA recommends that CMS take measures to ensure this application and/or the interface to the codes will be updated in a timely manner as codes change on an annual basis.

d. **B. Other Diagnoses, Comorbidities, and Complications**–If a V-code is listed, also list the medical diagnosis and the ICD-9 CM code for the medical diagnosis.

- AHIMA is concerned regarding the instructions identified in this section as it would violate the official coding guidelines. For many V codes, it would not be appropriate to list a medical diagnosis in conjunction with them. For many V codes, there would be no applicable medical diagnosis. For example, there are V codes for personal history of cancer of various sites. These codes mean the patient no longer has cancer, so assigning a cancer diagnosis code would be inappropriate. For example, there are V codes that indicate certain status situations, such as the fact that the patient has had an organ transplant. The patient may or may not still have the condition that led to the transplant. There are V codes indicating the patient has an artificial opening, such as a colostomy. The patient may or may not still have the medical condition that led to the colostomy.
  - There is a V code for encounter for surgical dressing changes. However, there is no medical diagnosis code that can be reported in conjunction with this V code because there is no diagnosis code for “surgical wound.”
  - There are V codes indicating exposure to certain diseases. Since the patient has not developed the disease, there is no appropriate medical diagnosis to report with these V codes.
  - There is a V code for asymptomatic HIV infection status. Again, there is no medical diagnosis to report with this V code.
  - The official coding guidelines state that aftercare codes (V codes) cover situations when the initial treatment of a disease or injury has been performed and the patient requires continued care during the healing or recovery phase, or for the long-term consequences of the disease. If the acute condition no longer exists (for example, neoplasm eradicated, gallbladder removed), or the condition is no longer receiving active treatment (for example, fracture aftercare, surgical and medical treatment for cancer has been completed), the code for the acute condition should not be assigned. Only the appropriate aftercare V code should be assigned. The coding guidelines specifically stipulate that fractures should be coded using the aftercare codes after the patient has completed active treatment of the fracture and is receiving routine care for the fracture during the healing or recovery phase. An exception would be care of complications, whereby the appropriate complication code should be assigned instead of the aftercare code. If there is a need to capture the original acute diagnosis on the PAC assessment, it should be captured in a separate data element.

- OASIS instructions state that the current ICD-9-CM guidelines should be followed in coding the diagnosis code items on OASIS. There are very detailed coding principles for coding the OASIS diagnosis code items. AHIMA is concerned regarding how HHAs report case mix diagnosis per the OASIS guidelines?

- The use of V codes is governed by the ICD-9-CM Official Guidelines for Coding and Reporting. If a patient is admitted for surgical aftercare, list the relevant medical diagnosis only if it is still applicable. If it is no longer applicable (e.g., the surgery eliminated the disease or the acute phase has ended), then a V code, such as surgical aftercare is generally appropriate. For example, for a patient who had a hip fracture surgically repaired, coding guidelines stipulate that the acute fracture code can only be used for the initial, acute episode of care, which is why the acute fracture code is no longer appropriate once the patient has been discharged from the hospital to HH.

e. **C. Procedures**

- This section appears to apply more towards acute care. AHIMA is concerned that PAC settings will struggle with this section. For example, in the IRF setting, would physical, occupational, and speech therapy be reported here? These would normally not be reported. We recommend that a clearer definition is needed.

- Instruction "Did the patient have one or more therapeutic or major procedures *during this admission*?" It is unclear how this is completed if this is an admission assessment as they would not have had any procedures yet, particularly in a nursing facility. AHIMA recommends clarifying this question.

f. **D. Treatments**–AHIMA believes this section appears to duplicate some elements that might be reported in section C if they were performed in a PAC setting. The column entitled "Admitted/Discharged With:" is unclear and we are unsure when these items would be selected. If a patient had one of these items during their whole stay, would both columns be selected?

g. **E. Medications**–AHIMA is unclear why CMS would only capture admission data within this section and not include discharge data. It would appear to be a little inconsistent with the rest of the instrument, especially if the patient is being discharged home from a IRF or SNF and not receiving any other PAC services. We recommend CMS provide further clarification or reconsider the development of this section.

h. **E. Medications**–E31 "Is the medication list complete?" Medication lists/profiles are as complete as possible and updated when additional medication is added. AHIMA is unsure of the impact of this question and what purpose it might serve.

i. **G. Skin Integrity**–AHIMA recommends "unstageable" definition be the same as the proposed MDS 3.0 wording. As this is worded, it begins "full thickness tissue loss…." which is stageable. MDS 3.0 wording is: "Cannot be observed due to presence of eschar that is intact and fully adherent to edges of wound or wound covered with non-removable dressing/case and no prior staging known".

j. **H. Physiologic Factors**–This section of the form is somewhat confusing and could possibly serve as potential for many errors. This section of the CARE Instrument requires a large range of comprehension abilities to read and interpret information that is being requested. Having an individual completing the form chooses either H1 OR H2 for height; H3 OR H4 for weight will lend itself to many errors. The column for "Please Check if NOT Tested" will often be overlooked. AHIMA recommends that CMS reconsider the design and layout of this section of the CARE Instrument.

IV. Cognitive Status

a. **E. Behavioral Signs & Symptoms**–This section is used to document behaviors during the two day assessment period. AHIMA believes that documenting behaviors from just the past two days may be misleading. A patient may have been physically and verbally threatening for months, but may not exhibit those behaviors during the assessment period for any number of reasons (drugs, physical status, and so on.) The assessment instrument may not accurately reflect the patient's behaviors. We recommend that there be some way to document if the specific behaviors were present in the recent past, even if they are not present or exhibited during the two day assessment period.

b. **F. Mood**–It is unclear what a "mood interview" is. AHIMA would like clarification on whether there is a standardized test/question so that score has a value or some other method by which to measure.

c. **G.3. Pain Severity**

- It is unclear why there are two questions for pain severity as designated by G3 and G4. AHIMA recommends combining the two questions into one.
- The CARE Instrument asks the person completing the form to enter "8" (on a scale of 0–10) if the patient does not or is unable to answer. It is unclear whether the selection of an "8" represents the level of pain or just a non-answer. Reviewing the levels of pain severity scale for this question, there may be some confusion to the individual completing this section. For example, if the pain severity level "8" is selected does this mean that the level of pain is worse than the level "4" noted above? AHIMA recommends rewording or somehow clarifying to the individual completing this section that the "8" does or does not reflect a pain severity level.

d. **G. Pain**–Pain questions have a different scoring metric than what most healthcare providers are trained in. AHIMA recommends using the "faces" and Face, Legs, Activity, Cry, Consolability (FLACC) behavior pain assessment scale for non-verbal patients.

V. Impairments

a. **B. Bladder and Bowel Management**–It is unclear whether this section is to be completed or assessed upon admission. AHIMA recommends that this impairment have the ability to be scored on discharge as that may impact the level of care the patient requires.

b. **G. Grip Strength**–The terms "Normal" and "Reduced" are subjective if there is no data to compare to. AHIMA recommends using terminology similar to MDS.

c. **V and VI General**–AHIMA is concerned that the lack of FIM scoring will make it difficult for IRF providers to transition to a different scoring system and also initially affect accuracy and integrity of the data captured.

VI. Functional Status

a. **C. Supplemental Functional Ability**–The instructions state that the activities "must be observed"–this would be very challenging with regard to the needs for staffing coverage to "observe" a patient/resident making a light meal, performing light shopping, driving a car, using public transportation, and doing laundry. AHIMA recommends further clarification on this process or removing altogether from the CARE Instrument.

VIII. Frailty/Life Expectancy

a. The information captured in the section is extremely subjective rather than objective and would vary in data outcomes. AHIMA recommends removing this section from the CARE Instrument.

IX. Discharge Status

a. **D. Discharge Care Options**–The form does not allow an option of "discharge from where?" AHIMA recommends that an additional option be added to indicate where this information would be completed.

b. **E. Discharge Location Information**–There may be some instances where a patient is discharged to "self" or does not require further services. AHIMA recommends providing further clarification on how a user would identify these criteria for discharge status.

c. **E.5 Medicare Provider's ID number**–It is not clear how the number will be captured. Will the discharging provider have to call and obtain the receiving facility's identifying number? AHIMA believes that this process would be extremely time intensive to obtain and recommends further clarification on the requirement for this data. For example, if the staff completing this form does not have the identification number, can the form still be considered complete?

d. **E.6 In the situation that the patient or an authorized representative has requested this information not be shared with the next provider**–HIPAA allows information to be shared without consent if it relates to treatment, payment, or healthcare operations. Patients (or authorized reps) can request that protected health information NOT be shared in certain instances, but it involves a thorough process – a written request, review by the covered entity, approval of the request, and so on. AHIMA believes that given the potential timeframe to complete the assessment instrument, this section does not consider the necessary steps needed to adequately address the HIPAA regulations. We recommend the consideration of keeping this specific question out of the instrument.

e. **A.2 Items 3 and 4, D, E.2**–Even with specific instructions there is a high risk of interchanging these terms. A LTC facility or nursing home and a SNF is often the same building. "Nursing homes" often have skilled beds within; others are certified 100 percent for Medicare skilled care but don't have 100 percent skilled census. Discharging facility may not know the difference between the two and sometimes there is not a difference. AHIMA recommends further refining or clarifying the terms to ensure consistency and integrity of the data.

If AHIMA can provide any further information, or if there are any questions regarding this letter and its recommendations, please contact AHIMA's Director of Practice Leadership, Michelle Dougherty, RHIA, CHP (312) 233-1914 or michelle.dougherty@ahima.org, or me at (202) 659-9440 or dan.rode@ahima.org.

Sincerely,

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cc: Michelle Dougherty, RHIA, CHP
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