Comments on 8/10/11 CMS Draft Measure Methodology Report:
“Hospital-Wide 30-Day (All Condition) Risk Standardized Readmission Measure”

August 29, 2011

The National Association of Children’s Hospitals and Related Institutions (NACHRI) is pleased to have the opportunity to offer comments on the Draft Measure Methodology Report for the Hospital-Wide (All-Condition) 30-Day Risk-Standardized Readmission Measure. We offer these detailed comments in response to the Centers for Medicare and Medicaid Services (CMS) call for public comments, which was issued on August 22, 2011 with a response date of August 29, 2011.

The draft proposed Hospital-Wide Readmission (HWR) system has been developed as a possible next level approach to readmissions for the Medicare program for patients 65 years of age and older. Children’s hospitals treat relatively few Medicare patients, but the HWR proposal is of great interest because of the central role of Medicare in the U.S. healthcare delivery system and, specifically quality measurement, and because the proposal specifically speaks of adapting the HWR for all-payer datasets.

NACHRI has a number of concerns with the specific methods of the draft proposed HWR system, the overall approach of moving from a condition-specific system to an all-cause system, and the extent of testing and validation. NACHRI believes the approach should be incremental, learning from the initial approach that featured three high volume conditions and building on this with improved methods. NACHRI believes it is premature to move from a three condition system to an all-cause system (all causes except those that can very specifically be identified as planned).

We present a high level summary of NACHRI’s concerns and recommendations, focusing on the proposed outcome measure (all-cause 30-day readmissions), the four specifically requested areas for comment, the approach to testing and evaluation, and adaptation for all-payer application. Then, we present a brief overview on pediatrics and hospital readmissions, an outline of key concepts and principles for design of readmissions measurement systems, and a detailed set of comments, questions and suggestions for the 8/10/11 Draft Measure Methodology Report.

SUMMARY

1. Proposed Outcome Measure, Hospital-Wide (All Condition) 30-Day Risk-Standardized Readmission Measure: NACHRI does not support the proposed all-cause 30-day readmission system as a measure of hospital quality performance for public comparative reporting or payment. Rather, NACHRI supports the development of readmissions measurement systems that are focused on readmissions that are related to the conditions treated in the prior hospitalization and are potentially preventable by the actions of the hospital.

2. Definition of Planned Readmissions: NACHRI believes the proposed definitions for planned readmissions are conceptually flawed and the specifications are very incomplete. The concept of planned admissions is much too narrow to be the sole clinical basis for identifying hospitalizations to
be removed from the candidate pool of potentially preventable readmissions.

3. Inclusion and Exclusion Criteria: Five of the seven exclusion criteria are straightforward and logical given the purposes of the readmissions system. NACHRI has two recommendations.

   a. For the same reasons that PPS-exempt cancer hospitals are excluded from the proposed HWR system (“care for a unique population of patients that is challenging to compare to other hospitals”), NACHRI recommends that PPS-exempt children’s hospitals be excluded.

   b. NACHRI recommends expanding the exclusions for malignancy hospitalizations, and lowering the “high competing mortality risk threshold” in the 30 days post-discharge period from 50% to somewhere in the range of 25% based upon sensitivity analysis.

4. Definition of Index Admission Patient Cohorts: NACHRI does not support the use of the AHRQ Clinical Classification System (CCS) as the basis for defining patient cohorts. Many of the categories are very broad and heterogeneous, very little information is provided about the evaluation that led to the selection of the CCS, and the system is not regularly used by hospitals. It is also not clear how patients with multiple surgical procedures are classified. NACHRI recommends further exploration and testing of alternative classification methods.

5. Risk Adjustment: NACHRI does not support the proposed methods for risk adjustment. In NACHRI’s view, the proposed methods do not fully describe the reason for admission, the acuity of the index hospitalization, the full extent of complex chronic conditions, the impact of technology dependent conditions, or the impact of family, social and psychological factors. NACHRI recommends the development of a more robust clinical model, and one that will yield more recognizable and actionable information by users.

6. Evaluation and Testing: There is only a brief discussion in the proposal document about testing and evaluation. NACHRI believes it is essential that there be a full testing and evaluation of the proposed system. This should have two components: (a) statistical testing of readmissions patterns for biased subgroups of patients and hospitals, and (b) case level testing to ensure that the system is excluding and including the intended patient populations and that the readmissions represent cases that are potentially preventable by the actions of hospitals.

7. Adaptation of Proposed HWR System for All-Payer Applications: The proposed HWR system is developed specifically for the 65+ year old Medicare population, and NACHRI does not believe this can be easily adapted for all-payer applications. Evidence of this is that the less than 65 year old Medicare population (the SSI disabled) were excluded from the model development on the basis that, “younger Medicare patients represent a distinct population with dissimilar characteristic and outcomes.”

I. Brief Overview and Perspective on Pediatrics and Hospital Readmissions
Over the last several years, NACHRI and others in the pediatric community have been performing analyses to create a better understanding of the children who are hospitalized, those who are hospitalized more than once including short interval readmissions, the reasons for readmissions, readmissions that may be preventable, and risk factors for multiple hospitalizations. A number of articles are beginning to be published in the peer reviewed literature about pediatric readmission patterns (e.g., J. Berry, C. Feudtner, and J. Gay).

To briefly summarize, relatively few children are hospitalized and most children who are hospitalized have only one admission. However, there are subsets of children, mostly those with complex and multiple chronic conditions and technology assistive devices, who often have multiple hospitalizations. In children’s hospitals at least, multiple hospitalizations and short interval readmissions are dominated by children with complex and multiple chronic conditions. There are also readmissions for children with acute illness only conditions, but this is a relatively small part of total readmission activity. Initial analyses identify that most of the readmissions pertain to ongoing disease processes. Initial analyses (chart review level) link only a small percentage of readmissions to inadequacies in the inpatient care and discharge planning. There is some thinking that there may be greater opportunity for improvements through expanded care coordination services in the outpatient setting. This also will sometimes require agreement to pay for expanded care coordination services and home health services. There is much yet to learn about what is possible with the coordinated effort of all providers and payers.

Other important activity is occurring as a result of the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA). CHIPRA established a new AHRQ Pediatric Quality Measures Program with grants to Centers of Excellence to develop an expanded and enhanced set of core quality measures for children. This program began in early 2011 and includes projects to develop a variety of inpatient and outpatient quality measures, including pediatric readmissions measures.

Part of what NACHRI has learned from all this work is the tremendous complexity in understanding hospital readmission patterns and designing appropriate systems to measure what we are attempting to measure - i.e., potentially preventable readmissions. The effort needs to include methods to define distinct index admission patient cohorts, methods to classify and judge readmissions in terms of being related and potentially preventable, and methods to risk adjust for potentially preventable readmissions. To do this, all of the information on the hospitalization discharge abstract needs to be considered, not just principal diagnoses and procedures. In judging what is potentially preventable, the system must also judge what is significantly within the influence of the inpatient care providers versus outpatient providers and the larger care delivery system.

II. **Key Concepts and Principles for Design of Readmissions Measurement Systems**

NACHRI believes the following are key concepts and principles for the design of readmissions measurement systems. These concepts and principles serve as the framework for our detailed comments and suggestions on the CMS draft proposed HWR system.
1. Readmissions should be related to conditions treated in the prior hospitalization and to a significant extent should be potentially preventable.

2. Time windows for readmissions should be relevant and significantly within the influence of the hospital.

3. Readmissions systems should be tested and validated for the intended patient populations, especially subgroups that may be systematically at greater risk for readmissions.

4. The approach to the use of administrative data should seek to maximize the use of information from the index admission and certain information from the readmission hospitalizations (e.g., chronic conditions). In addition, the approach should incorporate information from prior hospitalizations when this is available and a practical option.

5. Fully developed risk adjustment methodologies are essential in rate-based measurements, such as readmissions. Otherwise, rate based comparisons will be biased, unhelpful and unfair. Risk adjustment needs to take into account:
   a. Reason for admission.
   b. Acuity of hospitalization, taking into account principal and secondary diagnoses and procedures.
   c. Complex and multiple chronic health conditions.
   d. Technology dependent conditions.
   e. To the extent possible - family, social, and psychological factors.

6. Readmissions systems should generate information about the potentially preventable readmissions that is clinically recognizable and relatively easy to interpret and act upon for improvement strategies.

III. Detailed Comments and Suggestions for 8/10/11 Draft Measure Methodology Report, “Hospital-Wide 30-Day (All Condition) Risk Standardized Readmission Measure”

1. Proposed Outcome Measure, All-Cause 30-Day Readmissions (Sections 1.1-1.3 and 2.1-2.2)

   The proposed outcome measure is, “unplanned all-cause 30-day readmissions after an admission for any condition”.

   It is NACHRI’s view that the unplanned all-cause 30-day approach to readmissions is much too broad, unfocused and unsubstantiated to serve as a measure of hospital quality for public comparative reporting or payment.
Introductory Sections 1.1-1.3 provide a general statement of rationale and Methods Sections 2.1-2.2 provide a more specific description and rationale for the proposed all-cause 30-day readmission measure, but neither in our view makes a convincing case for the proposal.

Section 1.2, Hospital-wide Readmission as a Quality Indicator, presents the proposal’s general perspective on hospital readmissions and the proposed outcome measure. Its opening statement to frame the topic is, “Hospital readmission, for any reason, is disruptive to patients and caregivers, costly to the healthcare system, and puts patients at additional risk of hospital-acquired infections and complications.” This perspective would support an all-cause 30-day readmission measure, but we don’t believe this is a fair or helpful framing of the topic. It could be said that almost all serious illnesses and all hospitalizations are disruptive to patients and caregivers, not just readmissions. This is not the issue. The issue is how to identify hospital readmissions that are likely preventable and within the significant influence of the hospital.

The last paragraph of Section 1.2 concludes, “Given that studies have shown readmission within 30-days to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, it is reasonable to consider an all-condition readmission rate as a quality measure.” We certainly agree that some readmissions for some patients can be prevented, but that does not substantiate a basis for the proposed all-cause 30-day readmission system to be a comparative quality measure of hospital performance.

The proposal document does not put forward its own analyses to substantiate the proposed all-cause approach. Rather, at the end of Section 2.2, Outcome Definition, the proposal puts forward six very general reasons for selecting an “all-cause” approach over a “related” approach. It cites that from the patient perspective, readmission for any reason is likely to be an undesirable outcome of care. We don’t think this is necessarily the case. Hospitalization may be what is needed and unavoidable to treat the patient’s condition. The question is not about whether the patient desires another hospitalization, but whether the subsequent hospitalization could have been prevented by the actions of the hospital. It then cites the difficulty of specifying a comprehensive list of all that may be considered “related” as a reason for not attempting to do this, but defining what is related and what is potentially preventable is the crux of the matter. If the readmissions measurement system does not try to do this, then how does the hospital know what the system is measuring and how does the hospital know how to best target their improvement efforts?

It is important to emphasize that it is not enough for the readmissions system to identify what is “related”. It must also identify what it considers to be “potentially preventable”. To illustrate, a patient admitted for treatment of cancer may be readmitted for conditions such as neutropenia or aplastic anemia. This is clearly related, but there may be little that is preventable about the readmission.

The rest of the reasons put forward are also very general and not very persuasive. It cites consistency with CMS’s existing measures, but this does not validate the existing measures, much less substantiate extending the same approach on a hospital-wide all-cause basis. It also cites encouraging broader hospital-wide approaches, but to do so does not require a hospital-
wide all-cause approach that does not target opportunities of greatest potential impact. Lastly, it cites the need to assess hospital performance against what is “expected”, but again since expected is defined without the rigors of what is related and potentially preventable, it’s hard to tell how meaningful this would be.

To summarize, NACHRI believes that readmissions measurement systems must focus on readmissions that are related and to a significant extent potentially preventable. NACHRI believes this is central to the validity and credibility of readmissions systems. This is probably the most difficult part of developing readmissions measurement systems, but cannot be skipped over.

The choice of time window (7, 15, 30 days) is another important parameter and has implications for what kinds of readmissions are included and how much the hospital can directly influence them. The longer the time frame the greater the influence of chronic conditions, family and social factors, and the organization, delivery and financing of outpatient and home care services. To illustrate, in one study of 15 day readmissions to a children’s hospital, it was identified that for 0-7 day readmissions a relatively higher percentage of cases were for acute illness only conditions, and for 8-15 day readmissions a relatively higher percentage of cases were for chronic conditions and planned hospitalizations.

The selection of time window is not straightforward or simple. It needs to be done in conjunction with the approach to what is counted as a potentially preventable readmission. The ideal system would tailor the time window to the specific measure. To illustrate, readmissions for infectious conditions that have short incubation periods such as bronchiolitis are relevant to include if they occur within one week of discharge. In contrast, patients admitted for ventricular shunt procedures may have obstructions that occur for a longer time after discharge and so a longer time window is justified.

If the readmissions system is not designed to accommodate different time windows, then adjustments need to be made. To illustrate, in the instance of bronchiolitis, if a one week time interval cannot be differentially specified by the system then bronchiolitis should only be allowed to count as a potentially preventable readmission in limited circumstances such as a readmission to a previous admission of bronchiolitis or closely related respiratory condition. Otherwise, the system is likely to be picking up mostly community acquired bronchiolitis, one of the more common causes of hospitalization in young children, and which is not attributable to the quality of inpatient care or discharge planning.

In the instance of the draft proposed HWR, the approach is all-cause, whether related or not, just as long as it is not specifically identifiable as planned. For this kind of system (which we do not support) or other very broad based systems in which attribution is uncertain and the intent is to use for comparative reporting or payment, we recommend that a 7 or 15 day time window rather than 30 days should be used at least until such time as it can be demonstrated that the longer time window is warranted.
The proposal document puts forward three reasons for a 30-day time interval in Section 2.2.2, but none actually substantiates the case, especially in the context of an all-cause system. The first reason stated is, “Within a 30-day time frame, readmissions are more likely attributable to care received during the index hospitalization and during the transition to the outpatient setting”. It goes on to say, “A number of studies have demonstrated that improvements in care at the time of patient discharge can reduce 30-day readmission rates”. These are both very general statements. No substantiation is provided for the initial statement that 30-day readmissions are “more likely attributable to care received during the index hospitalization and during the transition to the outpatient setting”, and no specifics are provided as to whether the impact of hospital activities is predominantly on the first week or two weeks after discharge versus the third and fourth weeks.

The second reason stated is that 30-days is consistent with other readmissions measures reported by CMS or by NQF. This may be true but doesn’t substantiate the other measures, and more importantly, doesn’t substantiate its application to this very broad all-cause context for hospital quality measurement reporting. It is important to distinguish that what may be helpful from a health plan perspective is different from that of an individual hospital, and what may be helpful for quality improvement may not be helpful for the purposes of comparison. A health plan is responsible for all services by all providers within its insured scope of benefits for its insured populations. Accordingly, it is useful for the health plan to examine all hospitalizations including hospital readmissions as part of its activity to track and assess utilization patterns for inpatient, outpatient, and home healthcare services. This is different than for a hospital which is providing inpatient services for selected patients and does not control the care delivery networks and providers or determine the covered services.

The third reason stated is a review and interpretation of “time to event” curves. It is difficult to view exact changes in readmission rates over time periods from Figure 1, but it is clear that there are many more readmissions in weeks one and two than weeks three and four, with probably about two-thirds of the readmissions occurring during the first two weeks. The conclusion statement is made, “Curves typically stabilize within 30 days of discharge, indicating that a 30-day cutoff is clinically reasonable”. It’s not clear how this statistical analysis leads to the conclusion that 30 days versus 20 days or 15 days or some other time window is best, but at a minimum this kind of analysis needs to be coupled with more in-depth analysis of the kinds of readmissions that are occurring in the third and fourth weeks and the extent to which hospitals can influence their occurrence. The application is also important to consider. If the results of the system are to be used for public reporting or payment for hospital services, then the measure needs to reflect what is reasonably within the control or influence of the hospital.

2. Definition of Planned Readmissions (Section 2.2.1)

Two kinds of planned readmissions are defined. One is readmissions in which a procedure from a pre-specified list of surgical procedures is performed, except that the procedure does not count as planned if the admission is for acute illness or complications of care. The second is readmissions for maintenance chemotherapy.
In NACHRI’s view, this overall approach to planned readmissions is conceptually weak. It also is incompletely specified, including only 33 of 103 AHRQ CCS surgical categories and only certain of the codes for chemotherapy.

The concept of planned readmissions is much too narrow to be the sole clinical basis for identifying hospitalizations to be removed from the candidate pool of potentially preventable readmissions. In the instance of surgical procedures, the operation may not always be planned but may be done on an urgent or emergent basis. That a surgical procedure is done on an urgent or emergent basis does not make it potentially preventable. There are many circumstances where a patient may be admitted to the hospital, treated medically, and then readmitted at a later time for surgery. It may often be the conservative approach to defer a decision about surgery or to give the patient more time. Subsequent hospitalizations for surgery can also be unrelated, either for trauma or unrelated illness.

To classify a readmission for surgery as a potentially preventable hospitalization, there needs to be specific clinical logic that identifies the situations viewed as potentially preventable. This is very different from the proposed approach of the HWR system which is to count all surgical readmissions except those that can be specifically identified as planned and removed from the system. To illustrate:

If the readmission for surgery is for a complication of care from the first hospitalization, then yes it is reasonable to count the readmission as potentially preventable. To assess this, it would be necessary to examine and make a judgment based upon the PDX of the readmission hospitalization or based upon the relationship of the surgery in the first hospitalization to the surgery in the second hospitalization.

The approach to chemotherapy is also narrow and limiting. The specifications only include the V code diagnoses for admission for chemotherapy and radiotherapy and procedures for therapeutic radiology for cancer treatment. It does not include other patients with procedure codes for receiving chemotherapy as part of their inpatient treatment. These are hospitalizations that are either “planned” or part of the treatment for the condition, and are not useful to count as potentially preventable readmissions.

More broadly we believe the approach to the classification of readmissions for cancer patients is flawed. The treatment for many malignancies involves multiple hospitalizations, often within short time intervals. A patient with an aggressive cancer may require very aggressive treatments with many side-effects and multiple hospitalizations, if they are ultimately to survive. Quality needs to be viewed moreso in terms of multi-year survival than short time interval readmissions.

To clarify, we are not saying that all admissions for all patients with any diagnosis of cancer need to be excluded from readmission measurement systems. To illustrate, it may be appropriate to include certain cancer patients receiving certain kinds of surgery, and cancer patients who are
not receiving chemotherapy provided they do not have certain more aggressive cancers or metastatic cancer.

The key point is the focus needs to be on potentially preventable hospitalizations and there needs to be a clinical model with detailed clinical specifications to distinguish these different circumstances. Otherwise, the system will produce a great deal of confusing and unhelpful output for users to sort through and try to make sense of.

In addition to our concerns about the conceptual approach to the use of planned procedures as part of the proposed HWR, we have concerns that the specifications of Table 1 Planned Procedure List is are incompletely developed.

There are some surgical areas that seem to be entirely missing from Table 1. These include:

- Brain surgery
- Other neurosurgery
- Eye surgery
- Ear, Nose, Mouth & Throat surgery
- Cranial-Facial surgery
- Liver surgery
- Pancreas surgery
- Spleen surgery

Among those surgical areas included in Table 1, there are a number of important surgical procedures that are missing. These include:

- Surgery for major congenital heart defects.
- Orthopedic surgery for fractures, dislocations, congenital deformities, and other diseases of hip & femur, low limbs and upper limbs (only hip and knee replacements and arthroplasty procedures are included).
- Many GI procedures such as appendectomies create esophago gastric sphincter competence, anal sphincter repair, colostomy, ileostomy, gastrostomy, et al. (only colorectal resection, gastrostomy and hernia procedures are included).
- Many kidney/urinary tract procedures such as correction ureteropelvic junction, ureterectomy, ureteroneocystostomy, cystostomy, bladder reconstruction (only nephrectomy and kidney transplant procedures are included).

Part of the problem with the Table 1 Planned Procedure List specifications derives from the surgical categories that Table 1 is built from. This is described further in Section III (4) of these comments, but in brief, Table 1 is built from the AHRQ Clinical Classification System which has 103 surgical categories, many very broadly defined, including 29 from residual other procedure categories. It is difficult to specify the logic for Table 1 without more discretely defined surgical categories.
In all, the Table 1 Planned Procedure List is missing many important and high volume surgical procedures. Many of these are done on a “planned” basis or are done for acute illness or trauma, but that does not make them potential preventable. As identified earlier, specific clinical logic needs to be developed, judging the relationship between surgical procedures in the index admission and readmission or based upon PDXes in the readmission, identifying that the second surgery is done as a result of complications from the first surgery.

If implemented in a complete and thorough manner, the number of short term readmissions for surgery that are potentially preventable would likely be a small subset of all short term readmissions that are potentially preventable. On the basis of the Table 1 Planned Procedure List, there will likely be many surgical readmissions falsely identified for inclusion in the HWR system. This will be compounded further by the Table 2 Discharge Condition Categories Considered Acute or Complications of Care. Diagnoses of acute illness should not cause a readmission for surgery to be considered a potentially preventable readmission, unless the judgment can be made that the acute illness is likely the result of inadequate care.

3. **Inclusion/Exclusion Criteria (Section 2.3.2)**

Seven exclusion criteria are defined. Many of these reflect the purposes of readmission measurement systems, are logical, and we support them. NACHRI does wish to offer two additional recommendations, but first a quick review of what we agree with.

We agree that patients who die should be excluded as they can no longer have a readmission. We also agree that patients transferred to another hospital or admitted for rehabilitation are planned or purposeful admissions and should be excluded. Also, patients who elect to be discharged against medical advice should not be counted as a readmission as they elected on their own to leave the hospital early.

The requirement that the patient be enrolled for 30 days past the hospital discharge date or have died during the 30-day period is also a logical requirement to implement the system.

The requirement that the patient be continuously enrolled for 12 months prior to the index hospitalization is an option available to the Medicare program, but as a cautionary note it is important to identify that this is not necessarily an option for other payors. It thus may not be practical to think that a model built with this information will be applicable for all-payer applications.

Medicare patients age less than 65 years are excluded. This is based upon the rationale that “younger Medicare patients represent a distinct population with dissimilar characteristics and outcomes”. We agree with this exclusion. Patients eligible for Medicare on the basis of being SSI disabled are a very different population, with different conditions, and likely different hospitalization patterns.
PPS-exempt cancer hospitals are excluded. This is based on the rationale that they care for a “unique population of patients that is challenging of compare to other hospitals”. We agree with this exclusion.

In addition, we recommend that PPS-exempt children’s hospitals also be excluded. The same rationale applies. In addition, there has been no attempt to include children’s hospitals patient discharges in the database for designing and testing the proposed HWR system, and no effort to refine the HWR to reflect the patient populations served by children’s hospitals.

The last exclusion is for patients with high competing mortality risk in the post discharge period. This is defined to be conditions with mortality greater than 50% in the 30-day post discharge period. In the 65+ year old Medicare population, this is mostly medical malignancy patients. It also includes one orthopedic cohort, patients who are admitted for fracture of neck of femur and do not receive a surgical procedure.

There is no question that these patients should be excluded. The quality signal would definitely be dwarfed by unavoidable severity of illness. The concern is that this exclusion is too narrow. A 50% mortality rate within 30-days of discharge is an extraordinarily high mortality rate. We have two recommendations. The first recommendation is an earlier recommendation to exclude broader groupings of malignancy patients from the proposed HWR system. The second recommendation is to lower the mortality threshold for this exclusion. Sensitivity analysis would be needed to assess more appropriate thresholds, but probably something in the range of 25% mortality would be more appropriate than 50%.

4. **Definition of Index Admission Patient Cohorts (Section 2.3.1 and Appendix Tables A, B and C)**

*Description of HWR Approach to Index Admission Patient Cohorts:*

To define index admission patient cohorts, the HMR proposal selected the AHRQ Clinical Classification System (AHRQ-CCS). The AHRQ CCS contains two levels of classification software for both diagnoses and procedures. The CCS single-level software contains general categories. The CCS multi-level software contains more specific categories. The HWR proposal chose to work from the single-level software with the more general categories.

Three reasons are given for selecting the AHRQ Clinical Classification System: “It is well known and widely used, 2) it is based on the principal diagnosis and not on complications or events that occur during hospitalization (unlike the Medicare Severity Diagnosis Related Groups [MS-DRGs], and 3) because the groups of ICD-9-CM codes within each category are more clinically homogeneous than other available groupers (MS-DRGs and CMS Condition Categories) and have relatively similar readmission rates.”

The proposal document elaborates a little on the first of these three reasons, but not the second or third. Regarding the first reason, it identifies that managed care plans, insurers and researchers have used the CCS for a variety of functions. It does not mention anything about
hospitals using the CCS, which is of concern since the intended application is a quality measurement and public reporting tool for hospitals.

The second reason cited is that the CCS is based upon the principal diagnosis and not on complications or events that occur during hospitalization (unlike MS-DRGs). This is unclear. If the HWR proposal wished to limit the information to diagnoses present-on-admission, it could do this with any classification system by limiting the data feed to principal diagnosis and secondary diagnoses present-on-admission. Whether this provides a sufficiently complete description for the purposes of the readmission system is an issue of concern, but the CCS proposal does not need to select the CCS to avoid capturing complications or events occurring during the hospitalization.

The other part of this that is not clear is the classification of patients with surgical procedures. How were patients who had multiple procedures classified? Many patients have multiple procedures and these include some of the more complicated surgical patients.

The third reason cited is that the CCS categories are more clinically homogeneous than other available groupers, with specific reference made to the MS-DRGs and CMS Condition Categories. There is no further elaboration of this statement. There is no explanation of how clinical homogeneity was evaluated, the criteria used, findings of relative strengths and weaknesses, or how its conclusions were reached. There is also no mention of other classification systems considered. This is a serious concern.

*Detailed description of the CCS medical categories and CCS surgical categories:*

*Medical patients* are assigned to one of 285 CCS single-level categories based entirely upon principal diagnosis. Secondary diagnoses and non-O.R. procedure information are not used. These 285 CCS categories and then aggregated into six broad service line groups defined as: neurology, cardiorespiratory, cardiovascular, oncology, medicine, and psychiatry.

Many of the CCS single-level diagnoses categories are very broad. To illustrate, there are categories that contain all congenital heart anomalies ranging from the simplest to the most complex, and likewise for anomalies of the nervous system, digestive system, genitourinary system, et al. Other examples of very broad categories include: Intracranial injury includes all skull and intracranial injury and concussion diagnoses, with or without bleeding and with or without coma. Burns include all burns of all sites, 1st degree, 2nd degree, 3rd degree, and deep 3rd degree. Development Disorders includes diagnoses ranging from stuttering and learning disorders to development delay, mild mental retardation and profound retardation. Paralysis includes hemiplegia, all forms of cerebral palsy, quadriplegia, paraplegia, monoplegia and transient paralysis in limb. Coagulation and Hemorrhagic DXes includes all such diagnoses ranging from the simplest to most complex.

There are also many residual “other diagnoses condition” categories that are even broader and more diverse. “Other Nutritional, Endocrine and Metabolic Disorders” includes major inborn errors of metabolism, minor dietary metabolic disorders, failure to thrive, a variety of signs and
symptoms diagnoses, and V codes for body mass index from high to middle-of-the-range to low. “Other Nervous System Disorders” include sleep disorders, pain diagnoses, carpal tunnels, peripheral neuropathies, encephalopathy, muscular dystrophy, lack of coordination/ataxia, a variety of neurologic signs and symptoms, history-of V codes, and ventricular shunt status. “Other Congenital Anomalies” contains a wide range of body systems and a very wide range of conditions by severity and multiple body system involvement.

The more specific categories also often contain a wide spectrum. For example, HIV contains HIV disease and asymptomatic HIV infection. Leukemia includes acute leukemia and chronic leukemia, myeloid and lymphoid leukemia, and all DX codes whether in remission, not in remission, or in relapse. Hepatitis includes chronic and acute hepatitis, with coma and without coma. Diabetes with complications includes all codes whether chronic or acute. Acute myocardial infarct includes all DX codes whether for the initial acute episode or subsequent episode. Conduction Disorders include 1st, 2nd, 3rd degree blocks, pacemaker status, and defibrillator status.

Surgical patients are identified through the AHRQ CCS procedure categories. The AHRQ CCS single-level software has a total of 231 procedure categories. The HWR development team identified 103 of these categories to be for surgical procedures. All of these categories are aggregated into one very broad service line group, surgery/gynecology.

Some of the 103 surgical categories are for specifically defined surgeries, mostly high volume procedures, such as: coronary artery bypass, peripheral vascular bypass, gastrectomy, kidney transplant, bowel resection, colostomy, appendectomy, hernia repair, hip replacement, cholecystectomy, amputation of lower extremity, skin graft, nephrectomy, tonsillectomy & adenoidectomy, mastectomy, hysterectomy, and Cesarean section.

A second group of the surgical categories are for more broadly defined procedures such as incision/excision of central nervous system, heart valve procedures (open heart and percutaneous), and repair of fracture/dislocation/other disorder of hip & femur (same for lower limb and upper limb).

A third group, representing 29 of the 103 surgical categories, is for “Other Procedures” such as other upper GI procedures, other lower GI procedures, other GI procedures, other nervous system procedures, other heart procedures, other procedures of hemic and lymphatic system, et. al. These are extremely heterogeneous categories and very problematic.

To illustrate, “Other Heart Procedures” contains many of the most complex congenital heart repair as well less complex congenital heart repair, a wide assortment of open and closed heart procedures, insertion of heart assist systems, et al. Another category, “Other O.R. Procedures on Vessels Other Than Head & Neck” has more readmissions than any other surgical category, yet is extremely wide ranging and diverse.

An even more fundamental question raised earlier is how patients with multiple procedures are classified. The proposal describes how individual procedures are classified. However, there is
no mention of how surgical patients are classified. Are there surgical hierarchies? Are there
groupings or other methods that distinguish patients who have multiple procedures? How is a
full description of surgical patients provided?

**Summary of Concerns with the HWR Approach to Defining Index Admission Patient Cohorts:**

1. The CCS single-level categories for medical and surgical patients that are used are very
   broad, sometimes containing rather different conditions, and often conditions that vary
greatly in their acuity or complexity. Important differences are not captured, especially for
specialized medical conditions and surgical services.

2. It is not clear what analysis and evaluation led to the selection of the AHRQ CCS, or what
   consideration was given to other classification systems and methods. It is clear that on the
whole, these are broad and heterogeneous categories. It is of concern that a classification
system not regularly used by hospitals was selected for measurement of hospital
readmissions.

3. The principal diagnosis (PDX) for a hospitalization does not always capture the patient’s
   chief underlying health condition, the entire care team involved, and likelihood of future
hospitalizations. For example, patients admitted for PDXes of asthma or pneumonia who
have cystic fibrosis or bronchopulmonary dysplasia have very different hospitalizations and
their likely future hospitalization patterns are also very different. Patients admitted for
asthma, pneumonia, esophageal reflux, seizure disorder, hip & femur deformities, or
scoliosis who have cerebral palsy are very different patients involving a broad based care
team and are not well described by the six broad medical service lines.

4. There is no explanation of how surgical patients who have more than one procedure are
   grouped. There are many patients who receive multiple procedures, including many of the
more complex surgical patients.

   Does the HWR system actually group surgical patients? Or, are all the CCS surgical categories
that a patient has just passed to the risk adjustment regression model?

5. The groupings for surgical patients do not take into account the diagnostic conditions for
   which the surgery is performed. ICD-9-CM procedure codes are not always very specific and
using diagnosis codes together with procedure codes can help to distinguish more complex
surgeries. It can also identify conditions that are more likely to require ongoing care
including multiple hospitalizations.

6. The six medical service lines of the HWR proposal are very broad, and they do not all seem
to represent a distinct team of doctors, nurses, care coordinators, pharmacists, etc. For
example, asthma, pneumonia, COPD, and respiratory failure/insufficiency are grouped with
congestive heart failure in a service line for Cardiorespiratory on the basis that they are
clinically indistinguishable and typically treated by the same care teams. Then, cystic fibrosis
and other pulmonary diagnoses are grouped with Medicine. If this is helpful for a Medicare population, the same is not true for other patient populations.

The service line for Medicine is extremely broad. This includes eye, ear/nose/throat, cranial-facial, pulmonary, gastrointestinal, rheumatology, dermatology, endocrinology, nephrology, gynecology, hematology and immunology, infectious disease, burn, and trauma. This involves many different conditions, practitioners, and care teams. This does not seem to be a distinct care team. As such, it is hard to see how this would be helpful?

7. There is one service line for all of surgical services including gynecologic services. How it is it helpful to group all surgical specialties and care teams together?

8. In summary, NACHRI believes the CCS categories are overly broad and heterogeneous, and recommends further exploration and testing of alternate classification methods.

5. **Risk Adjustment:**

*Introduction:* The HWR risk adjustment model is designed to produce for each of seven hospital service lines, a summary risk adjustment score by calculating the volume-weighted logarithmic average of the predicted-over-expected ratios and multiplying the result by the average national readmission rate. To do this, the HWR model provides specifications for the following five items:

- Data Sources and Restrictions
- Index Admission Patient Cohorts
- Comorbidities
- Risk Adjustment Variables
- Statistical Approach

Following is a brief description and critique of these five items. The framework for the critique will draw from Section II of this document, “Key Concepts and Principles for Design of Readmissions Measurement Systems,” which put forward the following key components of hospital readmission risk adjustment:

- Reason for admission.
- Acuity of hospitalization, taking into account principal and secondary diagnoses and procedures.
- Complex and multiple chronic health conditions.
- Technology dependent conditions
- To the extent possible – family, social and psychological factors.

*Data Sources and Restrictions:* For the index admission patient cohorts, principal diagnoses (PDXes) are used along with procedure codes. Secondary diagnoses (SDXes) are not used. Please confirm that all procedure codes are used?
For comorbidities, diagnoses are used from the index admission except if viewed as potentially a complication. Diagnoses are also used from other hospitalizations during the past 12 months. Diagnoses from other settings are not used (because Medicare outpatient data is technically cumbersome to work with and outpatient data is difficult to obtain from all-payer datasets). Diagnoses from the readmission hospitalization are not used, not even chronic condition diagnoses.

NACHRI believes this approach leaves out key information from current hospitalizations that is likely to be relevant to the likelihood of a readmission. NACHRI also believes the proposed approach is overly dependent on historic data that will often not be available outside of the context of Medicare.

NACHRI recommends that for index admission patient cohorts, all principal and secondary diagnoses be used except if the SDX occurs after admission and is clearly identifiable as a complication of care, and also all procedure codes.

NACHRI recommends that for comorbidities, the model focus on all principal and secondary diagnoses from the index admission (except SDXes clearly identifiable as a complication of care), plus chronic condition diagnoses (PDX or SDX) from the readmission. NACHRI also supports the use of diagnoses from the past 12 months, especially chronic conditions, but this should be offered as part of an alternate supplemental module when the data is available and the basic model should not depend on the existence of 12 months of prior hospital discharge information for every patient.

Index Admission Patient Cohorts: This was discussed at length in Section III (4) of this document where we expressed our concerns that the CCS medical and surgical categories are overly broad and heterogeneous, and recommended further exploration of alternate classification methods. To this we add our concern that limiting the data source to principal diagnoses is overly restrictive.

Comorbidities: For comorbidities, the proposal selected the use of the CMS Condition Categories (CMS-CCs), except it excluded those occurring during an index admission if it felt these could potentially represent complications. The rationale for their selection is explained by the developers as, “We used CMS-CCs, the grouper used in previous CMS risk-standardized outcomes measures, to group ICD-9-CM codes into risk adjustment variables, since four CMS condition-specific claims-based readmissions models that use this have been validated against data that use charge abstracted data for risk adjustment.”

NACHRI has not previously reviewed the use of these CMS-CC categories for CMS risk adjustment models, but took a first look at these diagnosis categories to see how well they might capture diagnoses that NACHRI has observed to be important for analyses of readmissions for pediatric and all age patient populations. Following are highlights of our initial findings.

Some of the individual CMS-CCs appear to be fairly specifically defined, some are more broadly defined, and some contain a disparate set of diagnoses. The heterogeneity is probably greater.
for diagnoses common to younger populations but applies to a variety of CMS-CCs. For example, Renal Failure contains acute and chronic renal failure and stage I chronic renal disease through end stage renal disease. Decubitus Ulcer includes stage I though stage IV. Central Nervous System infections includes very extreme infections and much less serious infections such as viral meningitis NOS. Seizure Disorders includes complex epilepsy codes and febrile convulsions NOS. Other Development Disabilities includes learning disorders, certain emotional disorders, and congenital malformation syndromes affecting multiple body systems. Other Perinatal Problems Affecting Newborns includes mild symptom codes, twin status, and some serious acute illnesses. Serious Perinatal Problem Affecting Newborns includes a wide range of perinatal codes and also some very serious congenital anomalies.

A subset of the CMS-CCs was selected to be included among those used for the final risk-adjustment variables. These were then further aggregated into 15 CC groupings. The CCs selected appear to be conditions more common amongst elderly patients. Many conditions important for younger and all age populations were not included. There were also not any technology dependent categories included.

Also of concern is the aggregation of CCs that vary widely in their complexity. For example, schizophrenia, depression NEC, and other psychiatric disorders (mostly mild chronic or acute diagnoses or symptoms) were aggregated together. Infectious CCs were aggregated together that range from HIV, to a range of different central nervous system infections, serious opportunistic infections, and other infectious disease which includes viral enteritis. Diabetes with acute complications was aggregated with diabetes with chronic disease manifestations.

In sum, NACHRI has many questions and concerns about the CMS-CCs and how they are used in the proposed HWR system. NACHRI is especially concerned about the number of serious chronic conditions not included, the number of less serious and acute conditions that were included, the aggregations of conditions that vary greatly in their complexity, and the absence of technology dependent condition categories.

Risk Adjustment Variables: The HWR system includes the following variables in its regression methodology: age, index admission patient cohort (CCS), and comorbidities (CMS-CC). The proposal does not use socioeconomic status, gender, race, or ethnicity. The proposal also does not use admission source or discharge disposition.

Overall, NACHRI has a number of concerns about the adequacy of this approach. Most of the specific concerns have already been identified but to summarize very briefly:

- Reason for admission is not adequately described.
- Acuity of hospitalization is not adequately captured. Secondary diagnoses from the index admission are not even considered.
- Comorbidities are not fully reflected for complex and multiple chronic conditions.
- Technology dependent conditions are not provided for.
Family, social and psychological factors are not considered except for one aggregated comorbidity grouping of psychological diagnoses.

Statistical Approach: The one-week-to-respond time frame did not allow for close inspection of the statistical model but NACHRI has a concern with the overall approach as a complex statistical model rather than a clinical model.

It seems to be difficult to know what is driving the model, and the model will require ongoing recalibration for each database it is run on. In addition to rerunning all of the statistical algorithms, it seems that it would be necessary to respecify the diagnosis and procedure categories to capture conditions important to each population group.

NACHRI recommends the development of a more robust clinical model, and less dependence on statistical models. This will be easier for users to work from, and will yield more discrete and actionable clinical information for the user.

6. Testing and Evaluation

The HWR proposal document in Methods Overview Section 2.1 references evaluating the performance of the measure for various types of hospitals and groups of patients, but this is not presented, so we are unable to offer specific comments.

The proposal indicates that it plans to test the reliability of the proposed measure by randomly splitting the combined 2007 and 2008 data and comparing performance in each split sample. We are not clear as to exactly what will be tested, and what this is likely to demonstrate. It seems that the two random samples of 4,000,000 index hospitalizations will likely show similar patterns as the full dataset of 8,000,000 index hospitalizations. Additionally, it seems concerning that some of the same data used to develop the model will be used to test the model if we are interpreting the report correctly.

The proposal also indicates it will be testing the measure’s stability over time by comparing 2008 and 2009 performance. We’re also unclear what this will demonstrate.

NACHRI recommends that evaluation and testing occur at three levels.

(1) For statistical testing and validation, NACHRI recommends that emphasis be given to testing readmission patterns for biased subgroups of patients and hospitals.

(2) For case level testing from UB-04 discharge abstract data, NACHRI recommends that case level information be generated and evaluated to identify what kinds of cases being excluded and included (are these as intended?); and, whether these cases appear to represent readmissions that the hospital could likely have prevented.
(3) For case level validation from medical chart level information, NACHRI recommends testing be conducted to verify whether the exclusions and inclusions are truly identifying the intended populations; and, to verify that the readmissions do actually involve situations that the hospital could likely have prevented.