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June 24, 2013

Honorable Marilyn B. Tavenner, MHA, RN
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1599–P
P.O. Box 8011
Baltimore, MD 21244–1850

Submitted electronically via: http://www.regulations.gov

Re: CMS–1599–P
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation

Dear Administrator Tavenner,

The American Nurses Association (ANA) welcomes the opportunity to offer the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule: Changes Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (LTCHPPS) and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; and Hospital Conditions of Participation. The ANA, is the only full-service professional organization representing the interest of the nation's 3.1 million Registered Nurses (RN) through its constituent/state member associations, organizational affiliates, and individual members.

The ANA supports the use of rigorous structural, process, and outcome quality measures (Donabedian, 1988) that are effective tools in performance improvement, public reporting, pay for quality, and program evaluation in acute care hospitals and long term care hospitals. These core sets of measures should include patient-centric, team-based measures for use within settings (e.g., hospitals), and when appropriate aligned for use across settings as recommended by the Measure Application Partnership (MAP) and the Department of Health and Human Service's Measure Policy Council.

Acute Care Hospitals: **Measures for Payment Determinations relating to the Hospital Inpatient Quality Reporting Program, Value-Based Purchasing (VBP) Program, and the Hospital Readmissions Reduction Program.**

CMS is proposing refinements to the Inpatient Quality Reporting (IQR) Program for Acute Care Hospitals for Fiscal Years (FY) 2014, 2015, and 2016, further alignment of measures between IPPS and the pay for quality program, the Hospital VBP program, measures for the Hospital-Acquired Conditions (HACs) Reduction program, and new measures for the Hospital Readmissions Reduction Program.

A. Inpatient Quality Reporting (IQR) Program

CMS invites comments on what additional quality measures and information may be useful to patients and other consumers of healthcare. CMS proposes to continue its policy of publicly reporting data from the Hospital IQR Program as soon as it is feasible on the Hospital Compare or Medicare.gov websites. CMS proposes to make publicly available hospital level data for the eight component Agency for Healthcare Policy and Research (ARHQ) Patient Safety Indicators (PSI) as well as the composite measure, the PSI-90. CMS is proposing the Chronic Obstructive Pulmonary Disease (COPD) readmissions measure that assesses all-cause unplanned readmissions (excluding planned readmissions) rather than readmissions for acute exacerbations of COPD only for use in the Hospital IQR Program for FY 2014.

ANA Comments:

1) **Additional quality measures and information may be useful to patients and other consumers of healthcare**

The ANA's National Database of Nursing Quality Indicators® (NDNQI®) is the largest national database registry for nursing sensitive care, containing team-based data collected at the nursing unit level, across multiple unit types, in all 50 states and the District of Columbia. NDNQI is employed by one of every three hospitals in the U.S. (>1,900), with reports for over 18,000 units. NDNQI is a powerful tool to provide actionable, unit-level metrics to interprofessional health care teams to reduce HACs. The NDNQI reports on NQF-endorsed measures including measures that effectively address HACs via scientifically rigorous measures, such as the NQF-endorsed pressure ulcers and falls measures. The results include national-level reductions in pressure ulcers and injuries in NDNQI-participating hospitals.

NDNQI data reporting on these measures have been effectively used to support the Partnership for Patients (PfP) work towards progress to meet the national HACs reduction goal. Specifically, NDNQI provides national NDNQI comparison data for use by the Hospital Engagement Networks (HENs), including over 3,700 hospitals. The evidence generated through the use of NQF-endorsed gold standard measures informs hospitals in performance improvement. Specifically, the evidence provided by NDNQI research is informing the best practice bundles, processes of care as well as structures of care, to reduce HACs. For example, the researchers (Bergquist-Beringer et al., 2012 and in press) have shared the best practice bundles identified using NDNQI data to reduce pressure ulcers with the HENs in HEN-wide and national HEN PfP webinars. The use of consistent evidence-based tools, such as gold standard metrics, is important to inform clinical decision making, a component essential for a learning health system (IOM, 2012).

The effective use of these gold standard measures and the results, the reduction in pressure ulcers and falls, has been presented to leadership within CMS, the National Priorities Partnership, the Center for Medicare and Medicaid Innovation (CMMI) and senior White House staff. Consistent national use of these NDNQI gold standard measures is necessary to meet the bold national goal of 40% reduction of HACs. Thus, ANA specifically requests that CMS add the following NQF-endorsed, clinically-enriched pressure ulcer and falls measures to the IQR in FY 2014, 2015, and 2016: 1) NQF #0201 (nosocomial prevalence of pressure ulcers), 2) falls measures NQF #0141 and NQF #0202 (i.e., falls

and falls with injury rates). The timely addition of these best in class measures is essential for meaningful benchmarking across hospitals. This will also promote alignment in performance improvement for hospitals participating in the HENs and in all hospitals in the U.S.

CMS has indicated that consumers are also requesting key structural safety measures for transparent public reporting on Hospital Compare. For example, consumers are requesting the ANA staffing structural measures. These measures were recommended for re-endorsement by the safety experts in the NQF Safety Complications Steering Committee and the measures were re-endorsed by the NQF in 2012. Consumers understand the importance of these structural measures to safety outcomes and are requesting public reporting of the following RN staffing measures in IQR: 1) NQF #0205 - Nursing Care Hours Per Patient Day (RN, LPN, and UAP) and 2) NQF #0204 - Skill Mix (Registered Nurse [RN], Licensed Vocational/Practical Nurse [LVN/LPN], Unlicensed Assistive Personnel [UAP], and Contract). It is essential that consumers, payers, purchasers and other stakeholders have access to this important safety data about hospitals given the significant shift from a volume-drive to a pay for quality environment. These measures support hospitals to implement ANA's *Principles for Nurse Staffing* (2012), which includes the identification of the major elements needed to achieve optimal staffing, which enhances the delivery of safe, quality care. The evidence for the ANA staffing measures to support quality care is included in Appendix 1.

2) Reporting of AHRQ Patient Safety Indicator (PSI) individual and composite measure (PSI 90)

ANA does not support the reporting of the PSI individual measures in IQR as they are not all endorsed by NQF (e.g., PSI-3 pressure ulcers). Additional comments on the PSI-3 and the AHRQ PSI 90 are provided in ANA's comments in the HACs Reduction program section below.

3) Additional Measures for IQR

ANA supports the proposed readmission (all-cause unplanned readmissions) and mortality measures for COPD that are NQF-endorsed measures that were supported for addition to the IQR program in FY 2014 by the MAP.

B. Value-based Purchasing Program

CMS proposes that all but one of the measures adopted for FY 2014 in the FY 2013 final rule be continued, and that three new measures are added. The measure that is not continued from FY 2014 VBP Program measure set is SCIP-VTE-1, (Surgery patients with venous thromboembolism prophylaxis ordered). The new measures include two outcome measures: AHRQ PSI 90, a composite of eight patient safety and complication measures, and a measure of central line-associated blood stream infection (CLABSI), and a Medicare spending per beneficiary, which is included in a new efficiency domain.

For FY 2016, CMS proposes to modify the domain weights used to calculate a hospital's total performance score so that clinical process of care measures would receive less weight (10% compared with 20% in FY 2015), HCAHPS would receive less weight (25% v. 30%), while more weight would be given to the outcomes (40% v 30%) and efficiency (25% v 20%) domains. For FY 2017, CMS proposes further alignment with the National Quality Strategy (NQS) priorities through additional domains and shifts in weighting.

CMS invites comments on what additional quality measures should be added to VBP.

ANA Comments:

1) **Modifications to the VBP measure set**
   CMS proposes to modify the VBP measure set for the FY 2016 payment determination. Previously, all of the FY 2015 measures were adopted for FY 2016, except for CLABSI. In this rule, ANA supports the CMS proposed changes 1) three measures for removal for the reasons CMS specified, 2) the continuation of the CLABSI measure, and 3) the three new measures. Specially, the ANA supports the addition of Catheter Associated Urinary Tract Infection (CAUTI) and Surgical Site Infection (SSI) as safety outcome measures and continuation of the CLASI measure. Data collection on these measures, which occurs through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) began for the IQR program with January 1, 2012 discharges. ANA also supports the addition of two additional measures to the FY 2017 VBP program in next year's rulemaking. These are the measures of Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia and the Clostridium difficile standardized infection ratio measures that were added to the IQR program measure set for reporting events beginning January 1, 2013.

   ANA does not support the continuation AHRQ PSI 90, a composite of eight patient safety and complication measures, in VBP for FY 2016 due to the limitations noted in the ANA's HAC Reduction Program comments.

2) **Future Measures for VBP**
   ANA specifically requests that CMS adds the following measure to VBP in 2015 and 2016: 1) NQF #0201 (nosocomial prevalence of pressure ulcers), 2) falls measures NQF #0141 and NQF #0202 (i.e., falls and falls with injury rates). As per the HHS Measure Policy Council, it is critical that CMS align across programs and settings, and when appropriate, include measures that are effective (e.g., demonstrate gold standard in the PfP and nationally-recognized reduction in HACs).

3) **Proposed VBP Weight Changes and Domain Categories**
   CMS has proposed changes in weights and domains for VBP. The shift in weighting from processes of care to outcomes is supported by ANA. ANA opposes the change in weights proposed for fiscal years 2016 and 2017 related to the reduction in the weighting for patient experience and the addition of the efficiency measure domain. The changes would devalue the worth of patient experience and increase the importance of an ill-defined efficiency measure for which there is no experience.

In particular, we believe that a health system that is labeled "Patient centered" has to devote more than one quarter of its final score to the patients' perception of how they were treated in the hospital. One could argue the weight should be 50% patient perception 50% assessments of the quality of care received. We recommend that the current weight of 30% be maintained in both fiscal years 2016 and 2017.

Research conducted by AHRQ and by RAND in refining the HCAHPS has demonstrated the validity of this set of measures. The RAND analysis showed that the most important of the components of HCAHPS is the nursing communication survey questions. There is no other measure used by CMS that reflects nursing input. Hospital staff nurses are invisible in the establishment of DRG rates. HCAHPS in this case serves a dual purpose.

The added weight proposed for the new efficiency measure seems unwarranted given the little detail that has been provided with respect to that measure. Medicare expenditures per beneficiary across an entire year makes sense; based on the average across individual discharges in a system based on DRGs seems more a simple measure of case mix rather than efficiency. Until there is some experience with the proposed efficiency measure for validation of its usefulness, there is no reason to expand its influence in the VBP calculations.

Additionally, ANA supports the shifting to align with each of the NQS priorities in 2017 as long as the safety measures are adjusted to include the NQF-endorsed pressure ulcer and falls measures used in NDNQI through expedited inclusion in the IQR and subsequent inclusion in VBP. These measures are effective, and meaningful at the unit level in hospitals (i.e., NDNQI gold standard safety measures noted above), where the true work of performance improvement occurs within interprofessional teams. It is important that progress is made to align with the NQS priorities using clinically enriched measures which are in eMeasure development (e.g., ANA has developed and is piloting a pressure ulcer eMeasure) which are in alignment with national evidence-based guidelines. Additionally, the MAP Safety/Care Coordination Task Force (MAP, 2012) identified the NDNQI pressure ulcer and falls measures as important measures for patient safety in accountability programs. Care processes that support good outcomes are different than care processes that prevent adverse events. They are conceptually distinct and should also be reflected in the VBP algorithm.

C. Hospital Acquired Reduction Program

ANA Comments:

ANA does not support the addition of the AHRQ PSI-3 pressure ulcer measure as it is not NQF-endorsed and lacks harmonization with the staging in evidence-based guidelines, including the National Pressure Ulcer Advisory Panel (2009) guidelines, which is endorsed by the ANA's organizational affiliate, the Wound Ostomy and Continence Nurses Society. As noted, the NDNQI pressure ulcer and falls measures have been effective tools for the PfP HENs in reduction of HACs and are in alignment with current evidence-based guidelines. Multiple stakeholders representing hospitals voiced support for the NDNQI pressure ulcer measure (NQF #0201) after NDNQI provided public comments in the MAP Hospital Workgroup meeting on 6/13/13. Thus, it is essential that CMS

include the NDNQI pressure ulcer and falls measures into IQR to expedite alignment of NQF-endorsed measures use across CMS public reporting and pay for quality programs.

The ANA does not support the addition or reporting of the composite HAC measure, the PSI-90, for inclusion in the HAC Reduction Program. Specifically, ANA does not support an alternative for individual reporting of the measures in the Domain 1 measure set consisting solely of the AHRQ PSI-90 composite measure. The PSI-90 is a composite of eight PSI measures: PSI-3, PSI-6, PSI-12, PSI-15 and PSI-7 (Central venous catheter related blood stream infections rate), PSI-8 (Postoperative hip fracture rate), PSI-13 (Postoperative sepsis rate) and PSI-14 (Wound dehiscence rate). First, the composite is appealing; however, the individual measures included involve complicated calculations and are not truly transparent for public consumption. Second, even though the PSI-90 is endorsed as a composite by NQF, it does not provide the level of specificity necessary for performance improvement in the reduction of HACs. Although a hospital may know its own rates for measures included in the composite, it will not have access to comparative information on the components. Therefore, hospitals and unit-based teams have less information on which to base performance improvement plans than if appropriate NQF-endorsed, clinically-enriched measures collected at the unit-level were reported separately.

ANA does support the proposed NHSN healthcare acquired infection (HAI) measures for the HAC Reduction Program for FY 2015, 2016, and 2017 currently listed in domain two. NDNQI is working with the CDC for efficient reporting of the NHSN HAI measures into NDNQI and at the request of the HENs to expedite this work. NDNQI provides a dashboard of structural, process, and outcome measures collected at the unit-level for effective unit-based HAC reduction for all HACs, including HAIs.

While it is certainly appropriate to separate AHRQ Patient Safety measures and CDC's HAI measures into two different domains based on their different measurement frameworks, in the long run it would be advisable to harmonize measurement to eliminate any potential of unintended emphasis. CMS noted the reasons for the different domains, citing the PSI-90 is collected using Medicare FFS claims data, collected at the hospital level, and only collected for adverse events among Medicare discharges versus the NHSN HAI measures which are collected using clinically-enriched, chart-abstracted data, collected at the unit-level, and collected for all adverse events. This categorization is a potential source of confusion related to differing scoring calculations for providers, consumers, payers, and other key stakeholders. The use of the NDNQI, NQF-endorsed pressure ulcer and falls measures would create alignment in measurement precluding the need for reporting using two separate domains.

D. Hospital Readmissions Reduction Program

Effective beginning in FY 2013, section 3025 of the ACA reduces payments to Medicare PPS hospitals with readmissions exceeding an expected level. The FY 2013 IPPS final rule established a new Subpart I under 42 CFR Part 412 (§§412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program. In the proposed rule for FY 2014 and beyond, CMS proposes to

– Refine the readmissions measures and related methodology for the current applicable conditions;
– Expand the "applicable conditions" for FY 2015

ANA Comments:

The ANA supports CMS' proposed changes to the program to apply the algorithm to the AMI, HF, and PN measures using the CMS Planned Readmission Algorithm Version 2.1. ANA supports the proposed Revised AMI/HF/PN Measures for FY 2014. CMS sought NQF endorsement of these revised measures for the three current applicable conditions (AMI, HF and PN), as required by the statute. NQF endorsed the revised AMI (NQF #0505) and HF (NQF #0330) measures in January 2013 and the PN measure (NQF #0506) in March 2013. For FY 2015, also ANA supports CMS's proposed expansion of the applicable conditions and procedures to include: (1) patients admitted for an acute exacerbation of COPD; and (2) patients admitted for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA).

Inpatient Psychiatric Facility Quality Reporting (IPFQR) program.
CMS proposes measures for FY 2014.

ANA Comments:

ANA supports the following comments provided by ANA's organizational affiliate, the American Psychiatric Nurses Association (APNA).

- While APNA understands the need to establish quality metrics to ensure that outcomes of care provided to individuals with mental illness is important we feel that the proposed additions to the already existing IPQRF will not achieve the desired outcomes and will be very onerous to manage for inpatient facilities.

- Related to the new IPFQR SUB-1 Alcohol Use Screening APNA has limited comment. The proposal indicates that facilities will screen for "unhealthy" alcohol consumption using a validated questionnaire. They identify that 4 alcohol/substance use measures that have been piloted and approved as a core measure set. Will these be the only tools that can be utilized or will other validated instruments be allowed is a question that needs clarification.

- Related to the new IPFQR SUB-4 Alcohol and Drug Use: Assessing Status After Discharge the concerns are numerous. It appears that the expectation is that the psychiatric facilities will have to contact the patients between 7 and 30 days post discharge to assess their alcohol and drug use status. One concern is in some facilities, safety net hospitals, which provide significant care to low-income, uninsured or vulnerable populations some of which are homeless or do not have easy means with which contact can be made post discharge. Despite the fact that in the proposal it excludes patients who do not have a phone or means of contact this is not always easily determined at admission or even

discharge. Thus in the record a phone number of a relative or other location may be identified but accessing the actual patient may be unrealistic. How will

the proposal address this concern that facilities may make many attempts and yet still be unable to access the patient? By eliminating the population of patients who have no access to phones or are unable to be contacted, the APNA has concerns regarding the reliability of the data and how this will address the reasons for this intervention.

- Related to the new IPFQR Follow-up After Hospitalization for Mental Illness the APNA's concerns are similar to those identified above plus the issue of added cost to the health system. The proposal requires the inpatient facility to contact patients either at 7 days or 30 days to determine that the scheduled outpatient encounter occurred. The purpose of this requirement is simply data collection and reporting. Both SUB-4 and this requirement will require inpatient facilities to hire one or more staff members, depending on discharge volume, to make discharge phone calls to patients.

- In the post discharge proposals, inpatient facilities will be placed in a position of case management of patients who are discharged for assessing relapse and outpatient follow-up. These are services that have not been reimbursed to inpatient facilities but are part of the reimbursement of outpatient providers such as community mental health centers. This will create some role blurring between care providers.

PPS-Exempt Hospitals Quality Reporting (PCHQR) program.
CMS has proposed measures to be added in 2016.

ANA comments:

The ANA supports the comments provided by the ANA organizational affiliate, the Oncology Nursing Society (ONS) below.

In regard to the six Oncology Care Measures proposed, the ONS supports these measures:

- Multiple Myeloma-Treatment With Bisphosphonates (NQF #0380)
- Radiation Dose Limits to Normal Tissues (NQF #0382)
- Plan of Care for Pain (NQF #0383)
- Pain Intensity Quantified (NQF #0384)
- Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low (NQF #0389)
- Risk Patients (NQF #0389)
- Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)

These NQF-endorsed measures appear unaltered from their form as reviewed in the past. ONS is pleased to see the two quality measures focused on pain assessment and management, as this is an essential area to address regarding an unfortunately pervasive

symptom in an oncology setting. The Multiple Myeloma and Adjuvant Hormonal Therapy in High Risk Prostate measures mirror the intent of the original 3 "basic appropriate treatment" measures selected for the PPS Exempt Cancer Hospitals reporting in 2014:

- (NQF #0559) Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer.
- (NQF #0220) Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer.
- (NQF #0223) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer.

The Radiation Dose Limit monitoring measure is appropriate and focused on the radiation department workflow and quality monitoring process improvement. The Avoidance of Bone Scan Overusage measure, though it appears to target the same department is really aimed at appropriate treatment decision making and ordering of diagnostics by the medical and surgical oncologists treating this patient population, and fits in with the joint campaign by the American Society of Clinical Oncology and American Board of Internal Medicine's Choosing Wisely project.

ANA looks forward to continuing activities with CMS related to improving the quality of care provided to all in America. If you have questions, or if the American Nurses Association can be of additional assistance, please contact Maureen Dailey, DNSc, RN, CWOCN, Senior Policy Fellow, by phone (301-628-5062) or e-mail (maureen.dailey@ANA.org).

Sincerely,

Marla J. Weston

Marla J. Weston, PhD, RN, FAAN
Chief Executive Officer

cc: President Karen A. Dailey, PhD, MPH, RN, FAAN

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Appendix

Table 1. ***Evidence of the Association between Nursing Hours per Patient Day and Patient Outcomes***

Patient Outcome	Author (year)	Staffing measure	Result
Falls	Blegen & Vaughn (1998)	Total nursing HPPD	NS
	Cho et al (2003)	Total nursing HPPD	NS
	Dunton et al (2004)	Total nursing HPPD	(-)
	Dunton et al (2007)	Total nursing HPPD	(-)
	Lake et al (2010)	RN HPPD	(-)
		LPN HPPD	(+)
		NA HPPD	(+)
Pressure Ulcers	Blegen et al (2011)	Total nursing HPPD	(-) Adult intensive care units only
	Cho et al (2003)	Total nursing HPPD	(+)
	Dunton et al (2007)	Total nursing HPPD	(+)
Failure to rescue	Blegen et al (2011)	Total nursing HPPD	(-)
	Needleman et al (2002)	RN HPPD	(-) Surgical patients only
Mortality	Blegen et al (2011)	Total nursing HPPD	(-)
	Needleman et al (2002)	RN HPPD	NS
Length of stay	Blegen et al (2011)	Total nursing HPPD	(-) Adult general units only
	Needleman et al (2002)	RN HPPD	(-) Medical patients only
Urinary tract infection	Cho et al (2003)	Total nursing HPPD	NS
	Needleman et al (2002)	RN HPPD	(-) Medical patients only
Pneumonia	Cho et al (2003)	Total nursing HPPD	NS
		RN HPPD	(-)
	Needleman et al (2002)	RN HPPD	NS

KEY. (-) statistically inverse relationship between nursing hours per patient day and patient outcomes (higher staffing is related to lower rates of the patient outcomes); (+) statistically positive relationship between nursing hours per patient day and patient outcomes (higher staffing is related to higher rates of the patient outcomes); NS = results were not significant; HPPD = hours per patient day; RN = registered nurses; LPN = licensed practical nurses; NA = nurse aides.

Table 2. ***Evidence of the Association between Nursing Staff Skill Mix (% of Hours Supplied by RNs) and Patient Outcomes***

Patient Outcome	Author (year)	Result
Falls	Blegen & Vaughn (1998)	(-)
	Cho et al (2003)	NS
	Dunton et al (2004)	(-)
	Dunton et al (2007)	(-)
Pressure Ulcers	Blegen et al (2011)	NS
	Cho et al (2003)	NS
	Dunton et al (2007)	(-)
Mortality	Blegen et al (2011)	NS
	Estabrooks et al (2005)	(-)
Length of stay	Blegen et al (2011)	NS
	Needleman et al (2002)	(-) Medical patients only
Urinary tract infection	Cho et al (2003)	NS
	Needleman et al (2002)	(-)
Pneumonia	Cho et al (2003)	(-)
	Needleman et al (2002)	(-) Medical patients only

KEY. (-) statistically inverse relationship between RN skill mix and patient outcomes (higher proportion of nursing hours provided by RNs is related to lower rates of the patient outcomes); (+) statistically positive relationship between RN skill mix and patient outcomes (higher proportion of nursing hours provided by RNs is related to higher rates of the patient outcomes); NS = results were not significant; HPPD = hours per patient day; RN = registered nurses.