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NATIONAL RURAL HEALTH ASSOCIATION

March 7, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1498-IFC2
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-3239-P, Medicare Program; Hospital Inpatient Value-Based Purchasing Program; Proposed Rule (Vol. 76, No. 9), January 13, 2011

Dear Dr. Berwick:

The NRHA is a national nonprofit membership organization with more than 22,000 members. The Association's mission is to provide leadership on rural health issues. The NRHA membership is made up of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health. We appreciate this important opportunity to comment on the Hospital Inpatient Value-Based Purchasing (VBP) proposed rule.

Nearly 20% of the U.S. population lives in rural America. This population contains a disproportionately high percentage of Medicare beneficiaries, poorer patients and patients with chronic disease. Rural hospitals, whether designated as Sole Community Hospitals (SCH), Medicare Dependent Hospitals (MDH), or otherwise, provide a critical service to rural residents who otherwise would have very restricted access to care. These hospitals provide excellent care and are committed to improving the safety, efficiency and the quality of care that they provide to their rural patients. Rural hospitals can and should be included in the Value Based Purchasing (VBP) program **as long as** equitable methodologies and measurements are developed that take into consideration the low-volume caseloads of rural facilities.

In general, the NRHA strongly supports the concept of aligning payment with the delivery of quality of care and supports the intent of the Affordable Care Act (ACA) and the proposed Hospital VBP proposed rule. Improved clinical quality for services delivered regardless of the size of hospitals or its location should be the goal of all. To attain that laudable goal, equity for all facilities regardless of size or location is paramount. Unfortunately, low patient volumes can lead to reported performance variation due to chance, not hospital performance. Therefore, CMS must take into consideration the unique challenges of the delivery of health care in rural America and the low patient volume of rural hospitals. CMS must establish appropriate measures and statistical analysis to ensure that low volumes do not significantly reduce measure reliability. CMS should consider new methods to achieve statistical reliability during performance analysis.

To this extent, if CMS is not successful at developing a statistically effective and equitable methodology for low-volume PPS facilities, the rural facility should have the opportunity to "opt out" of VBP requirements. The ACA also required that not later than March 23, 2012, the Secretary must establish two 3-year demonstration programs, one to test VBP models for critical access hospitals (CAHs) and the other for hospitals excluded from the VBP program due to an insufficient number of measures and cases. If CMS successfully develops an equitable and effective methodology in either one of these demonstration programs, a low-volume rural facility should be allowed to "opt-in" to that program once it is implemented. **Above all, low volume hospitals should not be penalized for non-compliance if CMS fails to create an equitable methodology for rural, low-volume hospitals.**

Additionally, the NRHA supports much of the thoughtful concerns and recommendations of the American Hospital Association (AHA), and wishes to highlight the following AHA recommendations and detail the importance to rural hospitals:

Proposed Performance Period. NRHA supports CMS' proposals for the fiscal year (FY) 2013 baseline and performance periods, which are both as long and as recent as possible under the ACA-mandated timeframes. This provision is especially critical for low-volume hospitals. Additionally, we join AHA's voice and urge CMS to fully recognize hospitals' improvements and achievements by implementing 12-month performance and baseline periods for all measures included in the VBP program.

Proposed Measures. The NRHA strongly opposes the inclusion of hospital-acquired condition (HAC) measures in both the VBP program and the HAC policy because of the opportunity for facilities to be penalized in a duplicative manner. We also urge CMS to use only National Quality Forum (NQF) endorsed measures, and not to include the mortality measure in the VBP program until the risk adjustment factor is further refined. Additionally, the NRHA reiterates its concern for proper consideration of low-volume hospitals and strongly urges CMS to refine the risk adjustment methodology to ensure that an equitable adjustment is made for these facilities.

Proposed Sub-regulatory Process: The NRHA strongly opposes the use of a sub-regulatory process to add measures to the VBP program. Such an addition would be extremely confusing to hospitals trying to use their VBP score for quality improvement, because the measurement time frame could vary significantly among the measures.

Proposed Performance Standards. Like the AHA, the NRHA strongly supports the work and assessments of Dr. Dale Bratzler, M.D., chief executive officer of the Oklahoma Foundation for Medical Quality, a leading quality improvement organization. We agree that quality measures for use in the first of the VBP program are not perfect, and can therefore not yield perfect results. The measures cannot incorporate all clinically relevant exclusion criteria based on every patient's particular situation, and may actually promote over usage which may not be beneficial to a patient. Furthermore, based on AHA's analysis, it appears that the achievement thresholds for most measures will be set at or above 0.90, which can prove to be detrimental to rural, low-volume hospitals. If such a hospital were to fail on its performance for a measure by just one patient, the rural hospital would automatically score below the achievement threshold and would not earn any achievement points for that measure. NRHA believes this is fundamentally unfair and urges CMS to change the methodology to better address the needs of low-volume hospitals.

Proposed Methodology for Calculating the Total Performance Score. The NRHA supports recommendations to simplify and improve the complex CMS' proposed formula for both achievement score and the improvement score. We support the mathematical recommendations of AHA as a method to develop a more straight-forward formula. Additionally, we strongly encourage CMS to lay out in a future proposed rule how it would apply the scoring models to the outcomes measures, especially for low-volume PPS facilities, before adding those measures to the VBP program.

HCAHPS. For rural, low-volume hospitals, it is consistently difficult to get an adequate number of returns in order to statistically meet HCAHP thresholds. Recent CMS changes in HCAHPS have made an already difficult threshold even harder. The NRHA urges CMS in the final rule to create an equitable methodology for low-volume hospitals, and to calculate the HCAHPS directly from the hospitals' scores on the measures, thereby creating transparency to hospitals and others. Again, excluding a large portion of small, rural hospitals from having sample sizes large enough to evaluate in this context could preclude them from taking advantage of significant benefits under VBP.

Applicability of VBP Program to Hospitals and Rural Demonstration Program. The NRHA supports CMS' proposal to exclude hospitals that receive a payment penalty under the pay-for-reporting program from the VBP program. Additionally, the NRHA asks for clarification as to whether subsection (d) hospitals that are in CMS demonstrations for their inpatient payment, such as the rural community hospital demonstration, will be included in the VBP program.

The Low-Volume Issue. The ACA excludes from the VBP program hospitals with small numbers of applicable patient cares or measures, as defined by the Secretary. The NRHA appreciates CMS' attempt to receive an independent analysis on this critical issue. It is imperative to accurately measure the minimum number of cases per measure and the minimum number of measures per hospital required to derive reliable performance scores. Therefore, the NRHA urges CMS to require the independent contractors tasked with the analysis to consult with a statistically valid sampling of rural, low-volume providers. We also encourage all proceedings to be open and transparent and that the final report be released to the public so that all stakeholders may evaluate the results. The NRHA strongly urges the Secretary to not release a final rule until an independent analysis is complete.

The Exchange Function. CMS proposes to translate each hospital's total performance score into an incentive payment using a simple linear scale, or exchange function. The NRHA agrees with AHA's assessment that VBP should reward providers for both demonstrating excellence in and improving quality and patient safety. It is again important to remember, however, that an equitable payment scale must be one that fairly measures a low-volume facility. The NRHA also strongly agrees with AHA's recommendation that incentives reach the hospital in the quickest manner possible, only then can they have a substantial effect on a hospital's ability to implement quality improvement activities.

Proposed Hospital's Notification and Review Procedures. The NRHA supports CMS' proposals for notifying hospitals of their estimated and actual incentive payments for FY 2013. We further ask that CMS clarify how it will apply this claims processing system to inpatient discharges retroactively.

Quality Improvement Organization (QIO) Quality Data Access. The NRHA shares AHA's concern that the proposed changes to access to QIO information may strip many of the current confidentiality provisions in place. We urge CMS to not make the proposed changes to the QIO regulations and to not allow the disclosure of QIO information to researchers.

The NRHA appreciates this opportunity and looks forward to working with CMS on this rule and the Value Based Purchasing rule regarding the two 3-year demonstration programs, one to test VBP models for critical access hospitals (CAHs) and the other for hospitals excluded from the VBP program due to an insufficient number of measures and cases. If you have any questions, please feel free to contact me or Maggie Elehwany at (202) 639-0550 or melehwany@nrharural.org.

Sincerely,



Alan Morgan
CEO
National Rural Health Association