Congress of the United States

Washington, DC 20515

May 22, 2008

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, D.C. 20201

Dear Acting Administrator Weems:

We are writing to express our strong opposition to language included in the FY 2009 Inpatient PPS Proposed Rule that would alter the longstanding practice of applying a national budget neutrality adjustment to the rural floor and therefore imputed rural floor of the wage index and replace it with a state-specific budget neutrality adjustment.

CMS' proposal to apply a statewide neutrality adjustment to the rural floor wage index would have severe adverse financial consequences for hospitals in our state. This proposal ultimately hurts all the hospitals in New Jersey and negates the benefits Congress intended for the rural floor to the wage index. The provision places undue and unnecessary harm on hospitals in our state with minimal benefit to hospitals in other states and harms the integrity of the Medicare payment system.

Budget neutrality must remain a national policy in accordance with current practice in order to retain balance and symmetry within a complex wage index environment. We encourage you to allow Congress to continue to fully examine and discuss an overhaul of the existing system instead of attempting to make changes such as these that do not address the fundamental problems and which could cause long-term harm to our hospitals.

Again, we urge you to eliminate the proposed state-level budget neutrality adjustment in the final FY 2009 Inpatient PPS Rule.

Sincerely,

Jim Saxton
Member of Congress

Frank A. LoBiondo
Member of Congress

Robert Menendez
U.S. Senator

Frank R. Lautenberg
U.S. Senator

Frank Pallone, Jr.
Member of Congress

Steven Rothman
Member of Congress

Rodney Frelinghuysen
Member of Congress

Robert E. Andrews
Member of Congress

Chris Smith
Member of Congress

Bill Pascrell, Jr.
Member of Congress

Scott Garrett
Member of Congress

Albio Sires
Member of Congress

Rush Holt
Member of Congress

Donald M. Payne
Member of Congress

Mike Ferguson
Member of Congress

Congress of the United States

Washington, DC 20515

June 13, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Weems:

We are writing to express our strong opposition to language included in the FY 2009 Inpatient PPS Proposed Rule that would alter the longstanding practice of applying a national budget neutrality adjustment to the rural floor of the wage index and replace it with a state-specific budget neutrality adjustment.

CMS's proposal to apply a statewide neutrality adjustment to the rural floor wage index would cut hospitals by almost $76 million in the State of California. Because this proposed rule change impacts reimbursement through Medicare, it disproportionately affects those hospitals in the State that treat a higher proportion of Medicare patients, which include some of California's most vulnerable institutions.

The provision places undue and unnecessary harm on hospitals in California and a few additional impacted states while according only minimal benefit to hospitals in other states. Elimination of nationwide rural floor budget neutrality also upends what has been CMS's consistent application of the budget neutrality requirement in effect since the rural floor was created as part of the Balanced Budget Act of 1997.

Budget neutrality must remain a national policy in accordance with current practice in order to retain balance and symmetry within a complex wage index environment.

Again, we urge you to eliminate the proposed state-level budget neutrality adjustment in the final FY 2009 Inpatient PPS Rule.

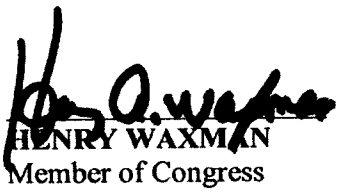
Sincerely,

MIKE THOMPSON
Member of Congress

DEVIN NUNES
Member of Congress

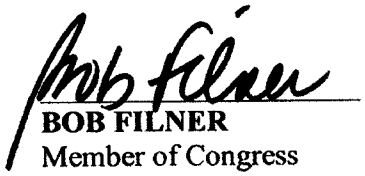
XAVIER BECERRA
Member of Congress

WALLY HERGER
Member of Congress

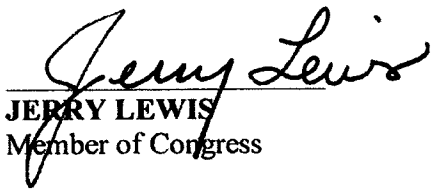


HENRY WAXMAN
Member of Congress

GEORGE MILLER
Member of Congress



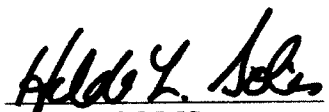
BOB FILNER
Member of Congress



JERRY LEWIS
Member of Congress

ANNA ESHOO
Member of Congress

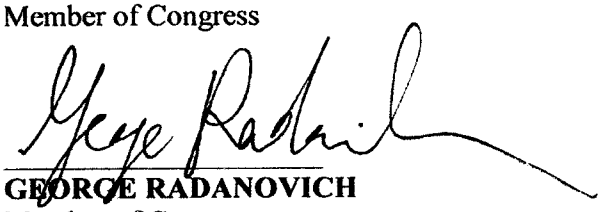
LOIS CAPPS
Member of Congress



HILDA SOLIS
Member of Congress

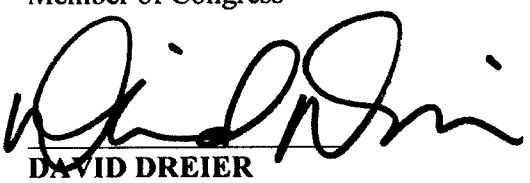
JANE HARMAN
Member of Congress

DORIS MATSUI
Member of Congress

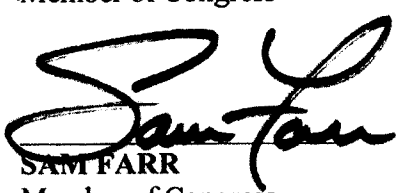


GEORGE RADANOVICH
Member of Congress

HOWARD BERMAN
Member of Congress



DAVID DREIER
Member of Congress

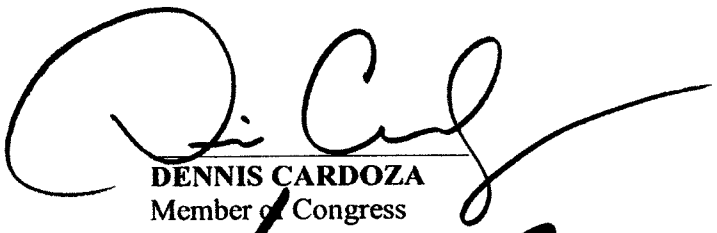


SAM FARR
Member of Congress

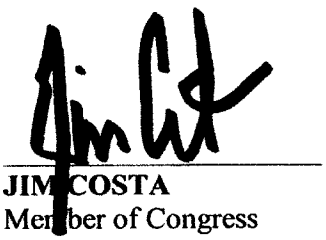
ADAM SCHIFF
Member of Congress

LUCILLE ROYBAL-ALLARD
Member of Congress

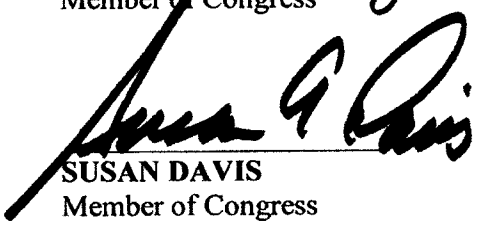
KEN CALVERT
Member of Congress



DENNIS CARDOZA
Member of Congress

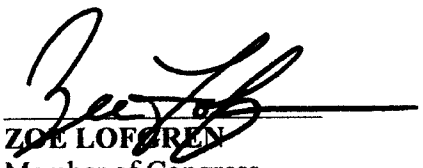


JIM COSTA
Member of Congress

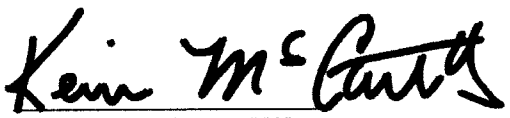


SUSAN DAVIS
Member of Congress

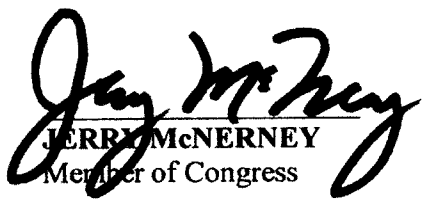
BARBARA LEE
Member of Congress



ZOE LOFGREN
Member of Congress



KEVIN McCARTHY
Member of Congress

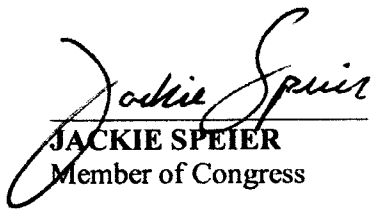


JERRY McNERNEY
Member of Congress

GRACE NAPOLITANO
Member of Congress

LINDA SANCHEZ
Member of Congress

LORETTA SANCHEZ
Member of Congress



JACKIE SPEIER
Member of Congress

LYNN WOOLSEY
Member of Congress

Mary Bono Mack

MARY BONO MACK
Member of Congress

Laura Richardson

LAURA RICHARDSON
Member of Congress

Congress of the United States
Washington, DC 20515

May 29, 2008

The Honorable Kerry Weems, Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Weems,

We are writing to express our strong opposition to language included in the FY 2009 Inpatient PPS Proposed Rule that would alter the longstanding practice of applying a national budget neutrality adjustment to the rural floor of the wage index and replace it with a state-specific budget neutrality adjustment.

CMS's proposal to apply a statewide neutrality adjustment to the rural floor wage index would have severe adverse financial consequences for hospitals in Connecticut. This change, coupled with the other changes proposed by CMS, would result in Connecticut experiencing a year over year cut in Medicare funding. If this rule stands, this will be the fourth time in the past twelve years that Connecticut has received a year over year cut.

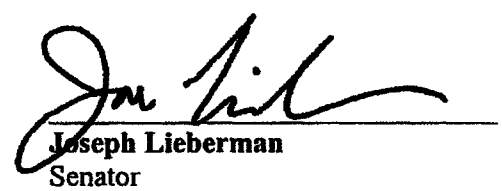
This proposal ultimately hurts all hospitals in Connecticut and negates the benefits Congress intended for the rural floor to the wage index. The provision places undue and unnecessary harm on hospitals in our state, which will be forced to carry a disproportionate share of the fiscal impact of the new rule. Under the rural floor adjustment, it is estimated that Connecticut hospitals will bear over twenty percent of all funding losses across the country.

Budget neutrality must remain a national policy in accordance with current practice in order to retain balance and symmetry within a complex wage index environment.

Again, we urge you to eliminate the proposed state-level budget neutrality adjustment in the final FY 2009 Inpatient PPS Rule and appreciate your consideration of our request.

Sincerely,

Christopher Dodd
Senator



Joseph Lieberman
Senator

Christopher Shays
Member of Congress

Rosa DeLauro
Member of Congress

John Larson
Member of Congress

Christopher Murphy
Member of Congress

Joe Courtney
Member of Congress

Congress of the United States
Washington, DC 20515

June 26, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Mr. Weems:

We are writing because we are greatly concerned about changes to the budget neutrality adjustment for the Medicare rural and imputed wage index floors in CMS' recent hospital inpatient proposed rule. We believe this change would be harmful to hospitals and run counter to Congressional intent, and we urge CMS to abandon this proposal and retain nationwide budget neutrality for the rural and imputed floors.

As proposed, within-state budget neutrality would be a radical departure from decades of CMS policy. Almost all Medicare provider payment systems, including the hospital inpatient prospective payment system has been nationally-based, including base payment amounts, conversion factors, payment factors / adjustments, and overall adjustments, including - most importantly - budget neutrality. In fact, in the 25 years since the inception of IPPS, we know of no situation where CMS has ever proposed a state-by-state adjustment.

Adjusting nationally rather than state-by-state has lent stability to the IPPS and we believe has been a key to its long term success. Spreading the impact of the many changes in the payment circumstances of individual providers across all providers nationally avoids dramatic changes and allows financial certainty for providers.

We believe this proposal sets a potentially harmful precedent, and we are concerned it could be used in the future for other regulatory adjustments. Switching to within-state budget neutrality, as CMS has proposed, creates the potential for drastic swings in individual reimbursements among the hospitals within a state. The policy could be discriminatory because it would allow CMS to add a painful local financial penalty on specific issues or in specific states simply by choosing to apply it budget neutral within the state rather than nationwide, even though the providers otherwise meet the criteria of existing policy.

We recognize that the current area wage index is an imperfect system. However, we have serious concerns that CMS's proposal to discontinue nationwide budget neutrality --one of the more successful and equitable aspects of the current system -- for the rural and imputed rural floors will have serious negative consequences for hospitals and runs counter to the intent of these provisions as well as Congress's desire to minimize the volatility of the wage index system. In light of the fact that Congress will be reviewing the recommendations made by MedPAC to "smooth" out the payment variations cause by the current Area Wage Index (AWI) system, this proposal certainly runs counter to direction of AWI reform.

We strongly urge CMS to maintain nationwide budget neutrality for the rural floor and all payment system and abandon consideration of alternatives based on within-state budget neutrality.

Sincerely,

Congress of the United States
Washington, DC 20515

June 23, 2008

The Honorable Charles Rangel, Chairman
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20003

The Honorable James McCrery, Ranking Member
House Ways and Means Committee
1139-E Longworth House Office Building
Washington, DC 20003

The Honorable Pete Stark, Chairman
Subcommittee on Health
House Ways and Means Committee
1102 Longworth House Office Building

The Honorable Dave Camp, Ranking Member
Subcommittee on Health
House Ways and Means Committee
1102 Longworth House Office Building

Dear Chairmen Rangel and Stark and Ranking Members McCrery and Camp,

As you know, on April 30, 2008, the Centers for Medicare and Medicaid Services (CMS) published its Medicare Inpatient Prospective Payment System (IPPS) rule for fiscal year 2009. We are writing to share with you our concern with language included in the IPPS that would alter the longstanding practice of applying a national budget neutrality adjustment to the rural floor of the wage index and replace it with a state-specific budget neutrality adjustment. While we understand that CMS is currently accepting comments on the IPPS rule and will make a final determination on the rule between now and August 1, 2008, we wanted to make you aware of the devastating impact this proposed rule would have on the hospital systems in our states.

CMS's proposal to apply a statewide neutrality adjustment to the rural floor wage index would have severe adverse financial consequences for hospitals in seven states – California, Connecticut, Iowa, New Hampshire, New Jersey, North Dakota, and Vermont. According to estimates, hospitals in these seven states will see the loss of over $150 million next year in Medicare funding. By choosing only to change the way it applies the rural floor wage index to a state-specific budget neutrality scheme, CMS is picking winners and losers.

We believe that CMS has made the decision to target the rural floor, rather than address the wage index in its entirety, because it believes the rural floor is the only portion of the wage index method that it can amend through regulatory rather than statutory action. This is an unsound piecemeal approach to modifying such an important element of how rates are determined and would be better addressed in a more comprehensive approach.

CMS's proposed change is a far reaching change to the wage index adjustment. We respectfully request that you monitor CMS's actions, and if necessary, consider legislative action to prevent CMS from implementing this proposed change.

The provision places undue and unnecessary harm on hospitals in our states, which will be forced to carry a disproportionate share of the fiscal impact of the new rule. Budget neutrality must remain a national policy in accordance with current practice in order to retain balance and symmetry within a complex wage index environment. We appreciate your attention to this matter and look forward to working with you to ensure fundamental fairness for our states' hospitals.

Sincerely,

Christopher S. Murphy
Member of Congress

John Larson
Member of Congress

Bill Pascrell
Member of Congress

Christopher Smith
Member of Congress

Jim Saxton
Member of Congress

Joseph Courtney
Member of Congress

Rosa L. DeLauro
Member of Congress

Christopher Shays
Member of Congress

Frank LoBiondo
Member of Congress

Albio Sires
Member of Congress

David Loebsack
Member of Congress

Paul Hodes
Member of Congress

Tom Latham
Member of Congress

Rodney Frelinghuysen
Member of Congress

Leonard Boswell
Member of Congress

Peter Welch
Member of Congress

Bruce Braley
Member of Congress

Robert Andrews
Member of Congress

Michael Ferguson
Member of Congress

Donald Payne
Member of Congress

Steve King
Member of Congress

Steve Rothman
Member of Congress

Rush Holt
Member of Congress

American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

June 9, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1390-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS).

While we support a number of the proposed rule's provisions, we have concerns about implementation of many of the new hospital quality measures, as well as payment cuts related to the wage index, capital payments and the post-acute care transfer policy.

HOSPITAL QUALITY DATA

The proposed rule would add 43 new quality measures for payment determination in FY 2010. This would, in one year, more than double the number of measures on which hospitals must report. **Adding such a large number of disparate measures is an unfocused approach to quality reporting that provides no direction to hospitals on quality improvement priorities.** Furthermore, this chaotic approach will adversely impact quality improvement efforts. In drafting this proposal, CMS has not followed the *Deficit Reduction Act of 2005* requirement that it choose measures that represent a "consensus among affected stakeholders," as it has proposed measures that are not endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA). It is important that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA. **Of the proposed measures, only 10 have been adopted by the HQA. We do not believe that the other 33 measures proposed by CMS are ready for reporting at this time.**

HOSPITAL-ACQUIRED CONDITIONS
In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher diagnosis-related group rate beginning in FY 2009 if the conditions were not present on admission. This year, CMS proposes to expand the list and include nine additional conditions when the payment policy takes effect on October 1. **Of the 17 total conditions, only four are ready to include for FY 2009.** The remaining conditions should not be implemented for FY 2009 because either they are not reasonably preventable, it is difficult to determine whether they are present on admission, or the patient population included by CMS is too broad.

OTHER PROPOSALS
We also strongly oppose the following direct payment cuts:

- Raising the threshold for wage index geographic reclassification, thereby making it more difficult for hospitals to qualify;

- Applying budget neutrality for the rural floor, imputed rural floor and geographic reclassifications on a statewide basis;

- Phasing out the indirect medical education adjustment to capital payments, which cuts payments to teaching hospitals by $1.3 billion over five years; and

- Expanding the post-acute care transfer policy to include patients receiving home health care services within seven days of discharge, which is estimated to reduce payments by $50 million in FY 2009 and $330 million over five years.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Joanna Hiatt, senior associate director for policy, at (202) 626-2340 or jhiatt@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

NJHA
NEW JERSEY HOSPITAL ASSOCIATION

June 6, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1390-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

On behalf of our 109 member hospitals, health systems and other health care organizations, the New Jersey Hospital Association (NJHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS).

While we support a number of the proposed rule's provisions, we have concerns about payment cuts related to the wage index, capital payments and the post-acute care transfer policy, as well as implementation of many of the new hospital quality measures.

HOSPITAL PAYMENT ISSUES
The NJHA strongly **opposes** the following direct payment cuts:

- **Applying the budget neutrality adjustments for the rural floor and imputed rural floor wage indexes at the state level rather than the national level**, which would reduce payments to New Jersey hospitals by $25 million;
- **Raising the threshold for wage index geographic reclassification**, thereby making it more difficult for hospitals to qualify;
- **Phasing out the indirect medical education adjustment to teaching hospitals**, which cuts payments to New Jersey teaching hospitals by $52 million for FYs 2008 through 2012 and, according to the American Hospital Association (AHA), cuts payments to hospitals nationally by $1.3 billion over five years; and
- **Expanding the post-acute care transfer policy** to include patients receiving home health care services within seven days of discharge. The AHA estimates this to reduce payments nationally by $50 million in FY 2009 and $330 million over five years.

HOSPITAL QUALITY DATA

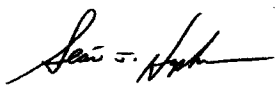
The proposed rule would add 43 new quality measures for payment determination in FY 2010. This would, in one year, more than double the number of measures on which hospitals must report. Adding such a large number of disparate measures is an unfocused approach to quality reporting that provides no direction to hospitals on quality improvement priorities. Furthermore, this chaotic approach will adversely affect quality improvement efforts. In drafting this proposal, CMS has not followed the *Deficit Reduction Act of 2005* requirement that it choose measures that represent a "consensus among affected stakeholders," as it has proposed measures that are not endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA). It is important that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA. **Of the proposed measures, only 10 have been adopted by the HQA. We do not believe that the other 33 measures proposed by CMS are ready for reporting at this time.**

HOSPITAL-ACQUIRED CONDITIONS

In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher diagnosis-related group (DRG) rate beginning in FY 2009 if the conditions were not present on admission. This year, CMS proposes to expand the list and include nine additional conditions when the payment policy takes effect on October 1. **Of the 17 total conditions, only four are ready to include for FY 2009.** The remaining conditions should not be implemented for FY 2009 because either they are not reasonably preventable, it is difficult to determine whether they are present on admission, or the patient population included by CMS is too broad.

Our detailed comments are attached. If you have any questions, please feel free to contact me at 609-275-4022 or shopkins@njha.com, or Roger Sarao, vice president, Economic & Financial Information, at 609-275-4026 or rsarao@njha.com.

Sincerely,



Sean J. Hopkins
Senior Vice President
Health Economics

New Jersey Hospital Association
Detailed Comments on the Proposed Rule
for the
FY 2009 Inpatient Prospective Payment System

HOSPITAL PAYMENT ISSUES

WAGE INDEX

The *Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006* (MIEA-TRHCA) required CMS to, taking the Medicare Payment Advisory Commission's (MedPAC) wage index recommendations into account, include one or more proposals for revising the wage index in the FY 2009 proposed rule.

Within-state Budget Neutrality Adjustment for the Rural and Imputed Floors. By law, the wage index for a hospital in an urban area of a state cannot be less than the wage index for a hospital in the rural area of a state. In addition, in 2006, CMS adopted an "imputed" rural floor measure by establishing a wage index floor for those states that did not have rural hospitals. Both the rural floor and the imputed rural floor are funded through a nationwide budget neutrality adjustment. For FY 2009, CMS proposes to apply a statewide (rather than a nationwide) rural floor budget neutrality adjustment to the wage index. The agency also is proposing to extend the imputed rural floor through 2011.

CMS has stated that the intent of the rural floor is to afford some measure of protection to urban-rural states; it created the imputed rural floor to do the same for all-urban states—a policy that the NJHA believes should be made permanent (and which we discuss in detail in a later section). However, despite the fact that these floors only affect certain states, they are nationwide policies. Applying budget neutrality on a nationwide basis minimizes the policies' impact on payments and results in the nation funding a nationwide policy. In contrast, applying budget neutrality on a statewide basis maximizes the policies' impact on the payments of a few hospitals, and results in several states funding a national policy.

The proposed budget neutrality adjustment for the rural floor and imputed floor wage index is inconsistent with other budget neutrality adjustments made by CMS within the inpatient PPS, which continue to be applied at a national level rather than a state-specific level (e.g., changes to DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). In the proposed rule, CMS indicates that it will fund a small rural community hospital demonstration project by offsetting the increased payment to these hospitals by an increase in the budget neutrality adjustment that will be applied across all inpatient PPS hospitals nationwide. We believe that CMS's proposal to apply the budget neutrality adjustment for the rural floor and imputed floor on a within-state basis reflects an inconsistency in policy that will place an undue burden on a small number of states.

Since its inception, the Medicare program has been national in scope. A proposal that would change the long-standing policy of having all hospitals in the nation share in the funding of a nationwide program, to one in which only several states fund select parts of a nationwide program and all states share in the funding of other parts, is a significant and potentially troublesome precedent. Despite the fact that the rural floor and the imputed floor provisions affect only certain states, they are nonetheless still a component of the national Medicare program.

The redistributive effect of applying the rural floor and imputed floor budget neutrality adjustments on a state-by-state basis would result in financial hardships and create operational difficulties for the hospitals located in the affected states.

In addition, the NJHA questions the timing of CMS's proposal to apply the wage index floor budget neutrality adjustments on a within-state basis. CMS has hired Acumen, LLC, to assist in its review of the current wage index system. Specifically, the two general responsibilities of Acumen are to (1) conduct a detailed impact analysis that compares the effects of MedPAC's wage and hospital compensation indexes with the CMS wage index and (2) assist CMS in developing a proposal (or proposals) that addresses the nine points for consideration under section 106(b)(2) of the MIEA-TRHCA (which instructs the Secretary of Health and Human Services to include in the FY 2009 inpatient PPS proposed rule one or more proposals to revise the wage index adjustment). In the proposed rule, CMS states that it will present any proposals resulting from the analysis in the FY 2009 inpatient PPS final rule or in a special Federal Register notice issued after the final rule is published. Given the larger context of the potential overhaul of the entire wage index system, it makes little sense for CMS to introduce significant policy changes that would adversely impact a small number of states.

The effects of within-state budget neutrality to the state of New Jersey are substantial. ***The NJHA estimates that New Jersey hospitals will effectively experience a cut of $25 million were this provision of the proposed rule to be finalized.*** This cut would be particularly devastating to the hospital industry in New Jersey, where 22 hospitals have closed since 1992, and six more have closed in the last 18 months. We have experienced a 30 percent consolidation of the industry in just the last two decades. Fully fifty percent of the hospitals that remain are currently losing money on operations.

Accordingly, the NJHA strongly opposes CMS's proposal to apply rural floor and imputed floor budget neutrality adjustments on a statewide basis. We also remain very concerned that CMS is continuing to introduce additional intricacies and changes to a wage index system that is already burdensome, inequitable and volatile.

Three-year Extension of the Imputed Floor. The NJHA applauds CMS for the language included in the FY 2009 inpatient PPS proposed rule that would extend the imputed floor wage index for all-urban states for an additional three years, through FY 2011. However, **we urge you in the strongest possible terms to make permanent the imputed floor policy that has led to a long-overdue climate of symmetry, equity and consistency in the Medicare reimbursement process for hospitals in New Jersey.**

Virtua West Jersey Health System
401 Route 73 North
50 Lake Center Drive, Suite 404
Marlton, New Jersey 08053

June 12, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1390-P, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

Virtua Health System appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for the fiscal year (FY) 2009 hospital inpatient prospective payment system (PPS).

While we support a number of the proposed rule's provisions, we have concerns about payment cuts related to the wage index, capital payments and the post-acute care transfer policy, as well as implementation of many of the new hospital quality measures.

HOSPITAL PAYMENT ISSUES
Virtua Health System strongly **opposes** the following direct payment cuts:

- **Applying the budget neutrality adjustments for the rural floor and imputed rural floor wage indexes at the state level rather than the national level**, which would reduce payments to New Jersey hospitals by $25 million. Even though Virtua Health would stand to benefit from the continuation of the imputed rural floor, we oppose state-level budget neutrality as misguided policy;

- **Raising the threshold for wage index geographic reclassification**, thereby making it more difficult for hospitals to qualify;

- **Phasing out the indirect medical education adjustment to teaching hospitals**, which cuts payments to New Jersey teaching hospitals by $52 million for FYs 2008 through 2012 and, according to the American Hospital Association (AHA), cuts payments to hospitals nationally by $1.3 billion over five years; and

- **Expanding the post-acute care transfer policy** to include patients receiving home health care services within seven days of discharge. The AHA estimates this to reduce payments nationally by $50 million in FY 2009 and $330 million over five years.

While Virtua Health supports the proposal to extend the imputed rural floor for 3 additional years, through FY 2011, we recommend that the policy should be made permanent for all of the reasons that we set forth in the detailed comments attached to this letter.

HOSPITAL QUALITY DATA
The proposed rule would add 43 new quality measures for payment determination in FY 2010. This would, in one year, more than double the number of measures on which hospitals must report. Adding such a large number of disparate measures is an unfocused approach to quality reporting that provides no direction to hospitals on quality improvement priorities. Furthermore, this chaotic approach will adversely affect quality improvement efforts. In drafting this proposal, CMS has not followed the *Deficit Reduction Act of 2005* requirement that it choose measures that represent a "consensus among affected stakeholders," as it has proposed measures that are not endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA). It is important that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and the HQA. **Of the proposed measures, only 10 have been adopted by the HQA. We do not believe that the other 33 measures proposed by CMS are ready for reporting at this time.**

HOSPITAL-ACQUIRED CONDITIONS
In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher diagnosis-related group (DRG) rate beginning in FY 2009 if the conditions were not present on admission. This year, CMS proposes to expand the list and include nine additional conditions when the payment policy takes effect on October 1. **Of the 17 total conditions, only four are ready to include for FY 2009.** The remaining conditions should not be implemented for FY 2009 because either they are not reasonably preventable, it is difficult to determine whether they are present on admission, or the patient population included by CMS is too broad.

DETAILED COMMENTS
Please see our detailed comments attached to this letter.

If you have any questions, please feel free to contact me at (856) 355-0605 jprosperi@virtua.org or Christine Gordon at (856) 355-0655 cgordon@virtua.org.

Sincerely,

Joe Prosperi / ccg

Joe Prosperi
Director of Budget and Reimbursement

Kerry N. Weems
June 12, 2008

Virtua Health System

Detailed Comments on the Proposed Rule for the FY 2009 Inpatient Prospective Payment System

HOSPITAL PAYMENT ISSUES

WAGE INDEX

The *Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006* (MIEA-TRHCA) required CMS to, taking the Medicare Payment Advisory Commission's (MedPAC) wage index recommendations into account, include one or more proposals for revising the wage index in the FY 2009 proposed rule.

Within-state Budget Neutrality Adjustment for the Rural and Imputed Floors. By law, the wage index for a hospital in an urban area of a state cannot be less than the wage index for a hospital in the rural area of a state. In addition, in 2006, CMS adopted an "imputed" rural floor measure by establishing a wage index floor for those states that did not have rural hospitals. Both the rural floor and the imputed rural floor are funded through a nationwide budget neutrality adjustment. For FY 2009, CMS proposes to apply a statewide (rather than a nationwide) rural floor budget neutrality adjustment to the wage index. The agency also is proposing to extend the imputed rural floor through 2011.

CMS has stated that the intent of the rural floor is to afford some measure of protection to urban-rural states; it created the imputed rural floor to do the same for all-urban states—a policy that VIRTUA HEALTH SYSTEM believes should be made permanent (and which we discuss in detail in a later section). However, despite the fact that these floors only affect certain states, they are nationwide policies. Applying budget neutrality on a nationwide basis minimizes the policies' impact on payments and results in the nation funding a nationwide policy. In contrast, applying budget neutrality on a statewide basis maximizes the policies' impact on the payments of a few hospitals, and results in several states funding a national policy.

The proposed budget neutrality adjustment for the rural floor and imputed floor wage index is inconsistent with other budget neutrality adjustments made by CMS within the inpatient PPS, which continue to be applied at a national level rather than a state-specific level (e.g., changes to DRG classifications, recalibration of the DRG relative weights, updates to the wage index, and different geographic reclassifications). In the proposed rule, CMS indicates that it will fund a small rural community hospital demonstration project by offsetting the increased payment to these hospitals by an increase in the budget neutrality adjustment that will be applied across all inpatient PPS hospitals nationwide. We believe that CMS's proposal to apply the budget neutrality adjustment for the rural floor and imputed floor on a within-state basis reflects an inconsistency in policy that will place an undue burden on a small number of states.

Since its inception, the Medicare program has been national in scope. A proposal that would change the long-standing policy of having all hospitals in the nation share in the funding of a nationwide program, to one in which only several states fund select parts of a nationwide

program and all states share in the funding of other parts, is a significant and potentially troublesome precedent. Despite the fact that the rural floor and the imputed floor provisions affect only certain states, they are nonetheless still a component of the national Medicare program.

The redistributive effect of applying the rural floor and imputed floor budget neutrality adjustments on a state-by-state basis would result in financial hardships and create operational difficulties for the hospitals located in the affected states.

In addition, VIRTUA HEALTH SYSTEM questions the timing of CMS's proposal to apply the wage index floor budget neutrality adjustments on a within-state basis. CMS has hired Acumen, LLC, to assist in its review of the current wage index system. Specifically, the two general responsibilities of Acumen are to (1) conduct a detailed impact analysis that compares the effects of MedPAC's wage and hospital compensation indexes with the CMS wage index and (2) assist CMS in developing a proposal (or proposals) that addresses the nine points for consideration under section 106(b)(2) of the MIEA-TRHCA (which instructs the Secretary of Health and Human Services to include in the FY 2009 inpatient PPS proposed rule one or more proposals to revise the wage index adjustment). In the proposed rule, CMS states that it will present any proposals resulting from the analysis in the FY 2009 inpatient PPS final rule or in a special Federal Register notice issued after the final rule is published. Given the larger context of the potential overhaul of the entire wage index system, it makes little sense for CMS to introduce significant policy changes that would adversely impact a small number of states.

The effects of within-state budget neutrality to the state of New Jersey are substantial. ***The New Jersey Hospital Association estimates that New Jersey hospitals will effectively experience a cut of $25 million were this provision of the proposed rule to be finalized.*** This cut would be particularly devastating to the hospital industry in New Jersey, where 22 hospitals have closed since 1992, and six more have closed in the last 18 months. We have experienced a 30 percent consolidation of the industry in just the last two decades. Fully fifty percent of the hospitals that remain are currently losing money on operations.

Though Virtua Health would stand to benefit from the continuation of the imputed rural floor, we oppose state-level budget neutrality as misguided policy, therefore VIRTUA HEALTH SYSTEM strongly opposes CMS's proposal to apply rural floor and imputed floor budget neutrality adjustments on a statewide basis. We also remain very concerned that CMS is continuing to introduce additional intricacies and changes to a wage index system that is already burdensome, inequitable and volatile.

Three-year Extension of the Imputed Floor. VIRTUA HEALTH SYSTEM applauds CMS for the language included in the FY 2009 inpatient PPS proposed rule that would extend the imputed floor wage index for all-urban states for an additional three years, through FY 2011. However, **we urge you in the strongest possible terms to make permanent the imputed floor policy that has led to a long-overdue climate of symmetry, equity and consistency in the Medicare reimbursement process for hospitals in New Jersey.**

CMS has already acknowledged the clear financial and competitive disadvantage suffered by all urban states in the absence of an imputed floor wage index. In its FY 2005 inpatient PPS proposed rule, it referenced the existence of one predominant labor market in New Jersey and acknowledged that this situation "forces hospitals that are not located in the predominate labor market area to compete for labor with hospitals that are in that area" and that "because there is no "floor" to protect those hospitals not located in the predominate labor market area from facing continued declines in their wage index, it becomes increasingly difficult to compete for labor."

The original CMS rationale reads as follows:

> We think it is also an anomaly that hospitals in all-urban States with predominant labor market areas do not have any type of protection, or "floor," from declines in their wage index. Therefore, we are adopting the logic similar to that articulated by Congress in the BBA and are adopting an imputed rural policy for a 3-year period. (pp. 49110-49111)
>
> *Ref: CMS-1428-F – Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates; Final rule (69 Federal Register 48916), August 11, 2004.*

We submit to you that New Jersey's geographic disadvantage remains as significant today as it was when CMS originally acknowledged the situation in the above comments. New Jersey is unique from the rest of the country in that it is bordered by the first and fifth largest cities in the United States. Therefore, New Jersey hospitals have been and continue to be forced to compete for labor resources and patients in each of these markets. CMS has provided no rationale for discontinuing the imputed floor policy after FY 2011, and has not provided any documentation that the aforementioned "anomaly" has been alleviated.

Based on the most recent data, the elimination of this vital provision would impact 26 New Jersey hospitals by $70 million annually beyond FY 2011.

The absence of the imputed wage index floor for all-urban states in the Medicare wage index calculation would once again subject New Jersey's hospitals to a significant competitive disadvantage and dramatically affect their ability to continue providing affordable, accessible and quality healthcare to the residents of our state.

Again, VIRTUA HEALTH SYSTEM urges you to make permanent the imputed rural wage index floor for all-urban states, instead of providing for a temporary three-year extension, in the final FY 2009 inpatient PPS rule.

Within-state Budget Neutrality Adjustment for Geographic Reclassification. Budget neutrality related to geographic reclassifications is also applied on a nationwide basis. However, CMS supports a legislative proposal that would apply this budget neutrality on a statewide basis. **We oppose statewide budget neutrality related to geographic reclassifications for the same reasons that we oppose statewide budget neutrality related to the rural floor.** Geographic reclassifications are necessary because the wage index system as a whole does not adequately reimburse hospitals their costs—its deficiencies necessitate numerous exceptions. Individual states—the very states where the wage index is most inequitable—should not be held accountable for paying for the entire system's deficiencies.

Revision of the Reclassification Average Hourly Wage Comparison Criteria. Each year, many hospitals apply for reclassification to another geographic area to receive a higher wage index. As part of its effort to propose wage index changes, CMS re-evaluated the average hourly wage (AHW) criteria for reclassification for the first time since they were established in FY 1993. Based on this analysis, CMS is proposing to change the criteria for FY 2010 and after so that an urban hospital would need an AHW that is 88 percent (up from 84 percent) of the area to which they want to reclassify. Hospitals applying for group reclassification would need an AHW that is 88 percent (up from 85 percent) of the area to which they want to reclassify. In addition, CMS is proposing to re-evaluate, and if warranted, recalibrate these criteria in the future when there are significant changes to labor market area definitions.

While CMS's proposal uses the most recent data, which VIRTUA HEALTH SYSTEM supports, it also raises the threshold for reclassification, thereby making it more difficult for hospitals to qualify. Making such a revision impedes hospitals' ability to offer competitive salaries to qualified individuals and, thus, provide the highest quality care and adequate access to beneficiaries. In addition, making these revisions without including additional funding simply moves the system's deficiencies around, rather than eliminating them. **Therefore, we oppose CMS's proposal to recalibrate the AHW criteria, both now and in the future.**

CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

In response to payment recommendations from MedPAC in FY 2006, CMS began significant efforts to reform the DRGs and the calculation of the corresponding relative weights. CMS started a transition to cost-based weights beginning in FY 2007 and a transition to Medicare-Severity DRGs (MS-DRGs) in FY 2008. In FY 2008, CMS also undertook an overhaul of the complications and comorbidity (CC) list to support three tiers of payment under the MS-DRGs based on the presence of: a major complication or comorbidity (MCC), a CC, or no CC. For FY 2009, CMS proposes to complete this transition with minimal methodological changes.

The hospital industry continues to support meaningful improvements to Medicare's hospital inpatient PPS. We believe VIRTUA HEALTH SYSTEM and CMS share the common goal of refining the system to create an equal opportunity for return across diagnostic groups, which will provide an incentive to treat all types of patients and conditions. We also believe the system should be simple, transparent and predictable over time. One of the fundamental values of a PPS is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. We are pleased that CMS has not proposed any major refinements to the methodology for the MS-DRG weights for FY 2009.

MS-DRG DOCUMENTATION AND CODING ADJUSTMENT

Potential Additional Payment Adjustments in FYs 2010 through 2012. The FY 2009 proposed rule applies the documentation and coding adjustment of negative 0.9 percent as required by the *TMA, Abstinence Education and QI Programs Extension Act of 2007.* ***Though mandated by***

legislation, these cut will adversely impact an already fragile hospital system in New Jersey by reducing Medicare payments by a combined $86 million for FYs 2008 and 2009, and by $514 million over the five-year period FY 2008 through 2012. This law also specifies that to the extent that the required adjustments for FY 2008 and FY 2009 result in overpayments or underpayments relative to the actual amount of documentation and coding-related increases, the Secretary will correct the overpayments or underpayments in FYs 2010 through 2012.

VIRTUA HEALTH SYSTEM is extremely concerned about the potential recoupment required by law. Determining how much of the total increase in case mix is due to changes in documentation and coding will be difficult and, if this determination is not made appropriately, it could result in overly large reductions to the standardized amount, which would ignore real changes in patient acuity and cause undue financial stress on hospitals.

VIRTUA HEALTH SYSTEM applauds CMS for recognizing the importance and challenges of this task by describing its preliminary analysis plans in the proposed rule and inviting public comment. Although the analysis plan CMS described is a good start, we believe it is insufficient to evaluate and quantify the various sources of case-mix change.

Many factors can contribute to case-mix change and careful analysis is required to determine the contribution of each factor. Changes in medical practice, demographics and health status over time affect case-mix growth, including:

- shifts in the site of service to hospital outpatient departments or ambulatory surgery centers, which could lead to higher hospital inpatient case mix if the patients shifted to other sites of service have fewer co-morbidities;
- aging of the Medicare population leading to increased co-morbidities;
- increasing severity of illness unrelated to aging of the Medicare population, such as rising rates of co-morbidities associated with higher levels of obesity; and
- changes in medical practice affecting average length of stay and the distribution of length of stay by MS-DRG or the intensity of services by MS-DRG

While the above factors lead to gradual change over time, more sudden shifts in case mix can occur because of specific policy changes. **VIRTUA HEALTH SYSTEM believes that a host of significant CMS policy changes occurring simultaneously with the implementation of the MS-DRGs has likely accelerated the case-mix growth rate.** For example:

- The implementation of present-on-admission coding is leading hospitals to assess patients for a broader array of conditions. This is likely to result in additional secondary diagnoses being identified, treated and coded, which involves a real increase in resource use and, therefore, real case-mix change.
- The permanent expansion of the Recovery Audit Contractor program is encouraging hospitals to even more carefully scrutinize low-acuity patients and shift care to the outpatient setting to avoid short-stay admissions. This change in practice will increase the average acuity of patients that remain in the inpatient setting.
- The implementation of Medicare Part D has resulted in acceleration of beneficiaries moving to Medicare Advantage. As detailed in the AHA's comment letter, Medicare

Advantage has been shown to attract the younger and healthier segment of the Medicare population, thereby increasing the average acuity level of the population that remains in fee-for-service Medicare.

- Effective in calendar year 2008, CMS made dramatic changes in the criteria for procedures that can be done in an ambulatory surgery center, thereby adding hundreds of additional procedure types. We believe that these changes will accelerate the move of lower-acuity patients to the outpatient setting, again resulting in increased acuity in the inpatient setting. The majority of ambulatory surgery centers involve physician ownership and self-referral, creating a strong incentive for shifts in site of service that did not exist when physicians were deciding between the inpatient and outpatient hospital setting.

While many of these types of factors were rigorously examined in the 1980s, VIRTUA HEALTH SYSTEM does not believe that the results of these old studies can be presumed to remain valid today (particularly in view of the magnitude of changes that have occurred both over the last 20 years and in the very recent past in Medicare policies, disease, technology, site of service, length of stay, post-acute care and other practice patterns). **VIRTUA HEALTH SYSTEM opposes any attempt by CMS to estimate real case-mix change based on old research or trends immediately prior to the implementation of MS-DRGs that assumes any residual change is the result of documentation and coding.**

REFINEMENT OF THE MS-DRG RELATIVE WEIGHT CALCULATION

Timeline for Revising the Medicare Cost Report. CMS stated that it has begun a review of the Medicare hospital cost report and plans to issue its proposed changes in the future. The Medicare cost report has become an antiquated instrument that no longer meets the needs of the current PPS or fits with the current accounting and management practices of hospitals. We agree that a re-examination is warranted and could help achieve simplicity by collecting only necessary information and ensuring that the cost report aligns with the current reimbursement methodology. In addition, we continue to believe that comprehensive cost report reform must be conducted in collaboration with the hospital field. However, we are unaware of CMS soliciting participation from either the AHA or other hospital field representatives. In the past, the AHA has suggested that efforts to comprehensively revise or replace the cost report should be mutual; we are concerned that such an effort has occurred unilaterally. **We are disappointed in CMS's failure to work with the hospital field from the outset on such an important endeavor.**

VIRTUA HEALTH SYSTEM urges CMS to avoid making piecemeal changes to the Medicare cost report that do not fully align with the current hospital protocols and reimbursement methodology. Doing so would not help accomplish our mutual goal of improving the accuracy of the cost-based MS-DRG weights. Further, depending upon the type of changes CMS proposes, it may not be possible for hospitals to alter their billing and accounting systems to capture the new data requirements after the start of their fiscal year. CMS must give adequate notice to hospitals to review and analyze comprehensive changes before they are implemented.

CAPITAL INPATIENT PPS

Medicare is required to pay for the capital-related costs of inpatient hospital services. These costs include depreciation, interest, taxes, insurance and similar expenses for new facilities, renovations, expensive clinical information systems and high-tech equipment (e.g., MRIs and CAT scanners). This is done through a separate capital PPS. Under the capital inpatient PPS, capital payments are adjusted by the same DRGs as are used in the operating PPS for each case. Capital PPS payments also are adjusted for indirect medical education (IME), disproportionate share hospital and outlier payments.

In the FY 2008 final rule, CMS made two changes to the structure of payments under the capital PPS, claiming that payments under the capital PPS exceeded what was required for hospitals to provide inpatient services. First, the agency eliminated the 3.0 percent additional payment that had been provided to hospitals located in large urban areas. Second, the agency adopted a policy to phase out the IME adjustment to teaching hospitals over three years. In FY 2008, teaching hospitals receive their full IME adjustment to capital payments; in FY 2009, they receive half their adjustment; and in FY 2010 and beyond, the adjustment will be eliminated.

CMS's elimination of the add-on payment for hospitals in large urban areas cut payments to New Jersey hospitals by $123 million from FY 2008 through FY 2012. Elimination of the IME adjustment will reduce payments to New Jersey teaching hospitals by an additional $52 million over the same five-year period **and, according to the AHA, will cut payments to hospitals nationally by $1.3 billion. These cuts are based solely on the discretion of the administration with no congressional direction and are unprecedented.** According to MedPAC, overall Medicare margins will be *negative* 4.4 percent in 2008. These cuts to an already under-funded system result in a decrease in capital payments that urban hospitals cannot sustain. ***As an entirely urban state, these cuts will be particularly devastating to New Jersey hospitals.***

Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments will create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America's seniors and disabled. CMS has no analysis of the impact of these proposed changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications. **VIRTUA HEALTH SYSTEM reiterates its opposition to these unnecessary cuts, which ignore how vital these capital payments are to investments in the latest medical technology, ongoing maintenance and improvement of hospitals' facilities and medical education.**

CMS justifies the cuts based on an analysis that purports to show that hospitals are experiencing substantial positive margins under the capital payment framework. The analysis, which averages

hospital inpatient Medicare capital margins for the period from 1996 to 2005, is deficient in several respects. What hospitals experienced in 1996 is irrelevant to the operating environment today, 12 years later. Looking at a snapshot rather than a full capital cycle of 15 to 20 years is misleading. The averaging system is meant to balance the high-spending cycles of some hospitals with the low-spending cycles of others over time, but isolating any given portion of the cycle may not achieve this. In addition, the regression establishing the capital PPS was based on total costs, not just capital costs, so CMS should be looking at total margins. As noted earlier, MedPAC estimates an overall hospital Medicare margin in 2008 of negative 4.4 percent. ***In New Jersey, the New Jersey Hospital Association's data shows that Medicare payments for an inpatient stay cover only 89 percent of a hospital's costs, on average.*** Whether or not hospitals experience a narrow positive margin for their capital payments is of small consequence to the hospital losing money, on average, every time it treats a Medicare beneficiary. Moreover, this should not be discussed in isolation from the overall payment effect in an effort to mask the fact that these are significant capital cuts.

CMS's analysis concludes in 2005, the year when the margin dropped to its lowest point, 3.7 percent, in the time period CMS selected. This 2005 margin is 30 percent below the 2004 capital margin and 51 percent below the 2003 capital margin. Extending that trend line projects that capital margins today are negative, which should not be a surprise because it is the very same overall Medicare margin trajectory that MedPAC has documented—a sharp decline since 2002—from positive 2.4 percent to an estimated negative 4.4 percent in 2008.

Hospitals must make a healthy positive margin in low-spending years in order to access loans and take on large, long-term financial obligations. Yet, CMS is suggesting that a very modest capital margin (3.7 percent in 2005, and likely lower today) is excessive. In 1991, CMS even stated that hospitals must accrue profits to supplement payments in high-spending years.
In addition, CMS has not fully considered the ramifications of dramatic capital cuts on the use of technology and the quality of hospital infrastructure. Reduced capital payments would make buying the advanced technology and equipment that patients expect much more difficult for the nation's hospitals, and could have the effect of slowing clinical innovation. ***These changes disadvantage large urban and teaching hospitals (both of which New Jersey has a high percentage relative to other states), where much of the innovation and cutting-edge research is generated.*** These hospitals will be even more challenged to keep up with leading technology, facilities and patient care. Moreover, for many hospitals, investing in information technology would become even more challenging. Without these facility and technological improvements, *all* patients will be deprived of these advances. At a time when the administration and Congress are pushing for such investments, this proposal may have the opposite effect of slowing needed adoption of health information technology.

POST-ACUTE CARE TRANSFER POLICY

VIRTUA HEALTH SYSTEM opposes expanding the post-acute care transfer provision to include patients receiving home health care services within seven days—rather than three days—of discharge, as it inappropriately penalizes hospitals for efficient treatment and ensuring that patients receive the right care at the right time in the right place.

Since FY 1999, Medicare beneficiaries in certain qualifying DRGs who are discharged to a post-acute care setting—including rehabilitation hospitals and units, long-term care hospitals and units, cancer hospitals, psychiatric hospitals, children's hospitals and skilled-nursing facilities—or are discharged within three days to a home health agency, are defined as transfer cases if their acute-care length of stay is at least one day less than the national average. These cases are paid a daily (per-diem) rate, rather than a fixed DRG amount, not to exceed the full PPS rate. Thus, if a patient has a shorter-than-average inpatient stay for certain DRGs, even by just one day, the hospital is paid less than the full DRG rate.

In general, this policy penalizes hospitals for the efficient treatment of patients. The Medicare inpatient PPS is a system of averages. Cases with longer-than-average lengths of stay tend to be paid less than costs, while cases with shorter-than-average stays tend to be paid more than costs. Expansion of the transfer policy further undercuts the basic principles and objectives of a PPS and only penalizes hospitals further. And, facilities in regions of the country where managed care has yielded shorter lengths of stay are disproportionately penalized.

The law states that the Secretary can pay as transfers those cases that are discharged to home health services "if the services are related to the condition or diagnosis for which the individual received inpatient hospital services, and if the home health services are *provided within an appropriate period* (as determined by the Secretary)" [emphasis added]. In 1999, the Secretary determined that three days was an appropriate period. CMS indicated that it was appropriate because it "mitigated the incentive to delay home health services to avoid the application of the post-acute care transfer policy, and because a three-day time frame was consistent with existing patterns of care."

The data and analyses that CMS present to suggest that the current three-day time frame is inappropriate are out of date and incomplete. First, CMS's analysis is based on home health agency claims from 1999 through 2003. However, in calendar year 2008, the home health PPS was substantially revised, in large part to address what CMS stated were "undesirable incentives from the 10-visit therapy threshold." CMS also stated that its analysis suggested that the 10-visit therapy threshold might have distorted service-delivery patterns. **Given that the home health PPS has recently undergone major modifications that will likely change future service-delivery patterns, we believe that CMS's use of data from the prior home health PPS in justifying a change to the transfer policy is inappropriate.**

Additionally, CMS stated that Medicare patients who are subject to the transfer policy are discharged earlier, and that it therefore expects that these patients should be less sick and thus less costly to the home health program. It then stated that this is not what the data show, as average Medicare payments per home health visit for patients subject to the transfer policy are consistently higher than patients not subject to the transfer policy. CMS stated that it found some evidence that hospitals may be discharging patients subject to the transfer policy earlier than advisable and providing less than the optimal amount of acute inpatient care. We find CMS's analysis deficient. The agency presents no analysis of patient case mix to support its claim. Instead, it presents evidence that payments per visit for patients subject to the transfer policy are higher than patients not subject to the transfer policy. We remind CMS that a

"payments-per-visit" statistic is affected not only by total payments, but also by number of visits. Patients subject to the transfer policy could very well be less sick, which would necessitate fewer home health visits, and in turn result in a higher payment-per-visit number when compared to their counterparts that were not subject to the transfer policy.

In the proposed rule, CMS suggests that hospitals are delaying the start of home health care past the three-day window in order to receive the full PPS payment. Yet there are a number of reasons home health services may be delayed to four days past discharge, or later. **The hospital discharge process is multifaceted and is influenced by a number of factors, including patient preferences, family availability, insurance coverage and access to post-acute care treatment options.** A delay in receiving home health services may occur because a patient's family is available to care for them the first few days after discharge. Or patients—especially medically complex patients—may need to wait for placement, as not all home health agencies have the capacity to take these patients. And, it is common for patients to be discharged on Friday and not receive a home health visit until Monday or Tuesday of the following week, given the intervening weekend.

This policy penalizes hospitals for making sound clinical judgments about the best setting of care for patients—and this setting is more and more frequently outside of the hospital's four walls. Home health services beyond the three-day window are not a substitute for inpatient acute care. Delaying services by seven days cannot be viewed as a "continuation of the inpatient admission," the justification Congress used in creating the post-acute care transfer policy. It is unreasonable to assume that a patient can go without professional care for a full week, then receive a nursing visit at home, and suggest that the patient is now continuing their inpatient acute care treatment, but in a different setting.

This proposal significantly expands the liability of hospitals for decisions that are not within their control. Hospitals often do not even know when a "transfer" to a post-acute setting occurs after a patient is discharged. This is because physicians, not hospitals, typically order and arrange such care. Patients may request that their primary care physician (someone other than their doctor taking care of them while they were in the hospital) arrange for home health services. And, it is not uncommon for a patient to be discharged home from the hospital, then to visit their physician a day or two later, only to have the physician order home health services that take another day or two to begin—again pushing the start of home health services past the three-day window. Patients discharged home, but who later receive a visit from a home health agency, should not be viewed as "transferred to home under care of a home health service organization in anticipation of covered skilled care." These patients have been discharged, and hospitals should not be penalized when valuable and cost-efficient, follow-up care is provided to these patients.

Expansion of this unreasonable provision actually creates perverse incentives to either keep patients longer, so that hospitals may retain the full DRG payment, or to delay home health services to after seven days of discharge—and neither is in the best interest of the patient. CMS suggests that some providers are "gaming" the system and intentionally delay ordering home health services until after the three-day window. If this were true, what evidence does CMS have that pushing the window to seven days would make a difference? There are other mechanisms in place to identify such providers (if they exist). Expansion of the transfer policy, which penalizes

all hospitals, is not the right answer. **The cost savings to the Medicare program of this proposal is minimal, yet the impact to patients and hospitals is very real.**

OUTLIER PAYMENTS

The rule states that CMS's proposed outlier thresholds for FY 2009 will yield outlier payments equal to 5.1 percent of operating DRG payments and 5.73 percent of capital payments. The AHA has been unable to successfully reproduce the cited capital outlier percentage of 5.73 percent. Instead, their analysis results in a capital outlier percentage of 5.37 percent. **Therefore, we recommend that CMS re-evaluate its calculation to ensure that the capital outlier percentage is correct.**

VIRTUA HEALTH SYSTEM appreciates that CMS has used a methodology that incorporates both cost inflation and charge inflation. However, CMS outlier threshold estimates continue to be overstated, resulting in significant and unreasonable payment cuts to hospitals. CMS is estimating that it spent only 4.64 percent, or about $400 million, less than what it set aside in FY 2007, and only 4.8 percent, or about $300 million, less than what it set aside in FY 2008. Using the proposed CCR-inflation methodology will continue to generate an inappropriately high outlier threshold as has occurred repeatedly in the past. VIRTUA HEALTH SYSTEM urges CMS to address the flaws in the methodology for estimating the outlier threshold.

HOSPITAL QUALITY ISSUES

HOSPITAL QUALITY DATA

The *Deficit Reduction Act of 2005* (DRA) expanded quality reporting requirements for hospitals to be eligible to receive a full market basket update and provided the Secretary with the discretion to add quality measures that reflect consensus among affected parties and replace existing quality measures on the basis that they are no longer appropriate. In the proposed rule, CMS puts forward 43 new measures to be included for the FY 2010 annual payment determination, which, in one year, would more than double the number of measures on which hospitals must report. To receive a full market basket update, hospitals would have to pledge to submit data on these and all measures currently included in the pay-for-reporting annual payment update program and pass the established data validation tests. The proposed measures include:

- One surgical care measure;
- Four nursing sensitive measures;
- Three readmission measures;
- Six venous thromboembolism measures;
- Five stroke measures;
- Nine patient safety and quality indicators from the Agency for Healthcare Research and Quality (AHRQ); and
- Fifteen cardiac surgery measures from the Society of Thoracic Surgeons registry.

Improvements in quality have been achieved by focusing on a few high-priority areas, understanding the steps that are critical to achieving the best outcomes, choosing measures that assess whether those steps are being performed reliably, testing and sharing strategies for enabling clinicians to reliably perform those necessary steps, and using the data to inform and motivate further action. Through the National Quality Forum (NQF), interested health care stakeholders come together to choose measures that are useful for these purposes. Through the Hospital Quality Alliance (HQA), public and private partners have come together to identify areas to focus on that are critical to hospitalized patients and, from among the NQF-endorsed measures, those that best assess quality in those selected areas. These two organizations are the primary consensus groups for hospital quality reporting. **In the proposed rule, CMS has not followed the requirement in the DRA that it choose measures that represent a "consensus among affected stakeholders," as it has not proposed measures that are endorsed by the NQF and adopted by the HQA.**

Expansion of the quality measures. **Adding 43 disparate quality measures in one year is an unfocused approach to quality reporting that will be detrimental to quality improvement.** With this broad list of disparate measures, there is no indication that CMS thought carefully or strategically about identifying the most important areas where resources and attention should be focused to advance quality and patient care.

Over the past few years, CMS has steadily incorporated a manageable number of new measures into the pay-for-reporting program. Hospitals have focused on each new measure and increased efforts in those areas each year. The results have been remarkable. Hospitals' overall performance has improved, sometimes rapidly, on every single measure added to the pay-for-reporting program. The national average score is now 85 percent or higher for more than half of the process measures that are currently reported. And those hospitals with the lowest baseline scores at the introduction of a measure have improved the most. This system has worked, and worked beyond expectations. By overwhelming hospitals with 43 new measures at one time, however, CMS is undermining that foundation of steady progress. Hospitals will not be able to make the same progress on these 43 measures that they have made previously. CMS's role is to provide hospitals with priority areas in which they should focus their quality improvement efforts, and the 43 measures in this proposed rule fail to do that.

Additionally, for performance measurement to foster quality improvement, the measures used must be actionable. Actionable measures are measures for which there are associated evidence-based practices that can improve patient outcomes. Such measures identify for providers exactly what evidence-based processes they did or did not follow, assisting them in interpreting and ascertaining where they can improve. If providers do not know what processes to change to improve patient care, measuring the care provided will make no difference. Some of the individual measures proposed by CMS are not actionable. Moreover, the very act of adding 43 new measures at once makes this whole set of measures unactionable for hospitals. **With this many measures, in a number of different areas of care, with different data sources, different degrees of reliability, different vendors with differing data collection instructions, different data collection schedules, and different validation processes, no organization can focus on where improvements are needed and implement the necessary changes.**

Hospitals are not the only audience that will struggle to make sense of this deluge of measures. The public already is struggling to understand and use the information on *Hospital Compare*. By adding many disparate measures, especially measures that are less reliable than those already on *Hospital Compare*, helping people understand what these data mean for their care, or for the care of a loved one, becomes an extraordinarily difficult task.

Even displaying data in a useful format lies beyond what *Hospital Compare* currently has the capacity to do. The current display of the data is not intuitive and is difficult for consumers to navigate. Through the HQA, we have been working with CMS on ways to improve the display of data on *Hospital Compare*, but opportunity remains to improve the Web site. With the addition of 43 new quality measures, the Web site will become even more cumbersome, and consumers may be discouraged as they try to find relevant information. Some of the proposed measures are very similar to existing measures and explaining the subtle difference between them to consumers will be a challenge. For example, with the addition of the 43 proposed measures, there would be five different measures that assess beta-blocker usage with slightly different, and sometimes overlapping, patient populations. Making sense of why all five are needed and which measures are relevant to a particular patient will be a challenge for clinicians as well as the public. The current format of *Hospital Compare* cannot communicate these distinctions.

One way to attain the needed focus is to use the priorities developed by the NQF's National Priority Partners. We are disappointed that CMS makes no mention of the work of this group. CMS should look to the Priority Partners' goals as a framework for the types of measures that should be included in the pay-for-reporting program. The goal of the national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The HQA has agreed that the NQF's national goals should provide a foundation for its future work. CMS should follow these national goals as well.

To collect data for 43 new measures, hospitals will have to devote substantial resources toward data abstraction and submission. The vast increase in work required for data abstraction will take resources away from patient care and other quality improvement efforts. For example, most hospitals employ nurses to perform clinical data abstraction. Nurses that perform data abstraction are not providing patient care. The explosion of new measures for FY 2010 will dramatically and suddenly increase the amount of required data abstraction work and may pull a greater number of hospital nurses away from providing patient care and into these paperwork duties.

Proposed quality measures. Most of the measures put forward by CMS have not been endorsed by the NQF and adopted by the HQA. **It is necessary that any measures added to the pay-for-reporting program first go through the rigorous, consensus-based assessment processes of both the NQF and HQA. Of the proposed measures, only the surgical care measure, the six venous thromboembolism measures and three of the nine AHRQ measures have been adopted by the HQA.** We do not believe that the other measures proposed by CMS are ready for reporting at this time. Our specific comments on each set of measures are included below.

- **Surgical care (perioperative beta-blocker usage)**—This measure has been endorsed by the NQF and adopted by the HQA. We believe it is appropriate for inclusion for the pay-for-reporting program for FY 2010. It is an addition to the existing surgical care measures.

- **Nursing sensitive measures**—These measures were previously adopted by the NQF; however, they had not been tested to ensure that consistent and reliable data collection was possible. Therefore, they are not ready for implementation for FY 2010. They are currently undergoing appropriate field-testing. Prior to inclusion in the pay-for-reporting program, all measures should undergo a field test to observe for any operational issues and assess the degree to which the measures can be implemented successfully by hospitals and data vendors. Those involved in the field-testing of these nursing sensitive measures indicate that substantial modifications will be needed before they can be broadly used to generate comparable data.

  The results of the field test will not be final until the end of this year. The results will lead to changes in the measures that may require NQF to re-examine the measures to ensure that they still meet the endorsement standards. We believe that these measures hold promise for future years, but because the field test is not complete, they are not ready for implementation for FY 2010. Additionally, we believe that the "failure to rescue" measure is identical to the AHRQ measure of "death among surgical patients with treatable serious complications." We ask that CMS clarify any distinctions between these two measures.

- **Readmission measures**—The heart failure readmission measure has been recently endorsed by the NQF, but has not been adopted by the HQA. Therefore, it should not be included for hospital reporting in FY 2010. The heart attack and pneumonia readmission measures have not been endorsed by the NQF and should not be included for hospital reporting in FY 2010 either.

  The HQA has adopted a measure of condition-specific readmission rates paired with condition-specific average length of stay (ALOS). As always, we urge CMS to look to the HQA as the source for applicable measures that are ready for inclusion in the pay-for-reporting program. CMS should incorporate the HQA-adopted readmission/ALOS measure into the pay-for-reporting program instead of the proposed readmission measures.

- **Venous thromboembolism measures**—The venous thromboembolism measures have been endorsed by the NQF and adopted by the HQA. They are ready for inclusion in the pay-for-reporting program. Venous thromboembolism is a major cause of mortality and morbidity for hospitalized patients, and hospitals have room for improvement in providing care for this condition. The Venous thromboembolism measures are a cohesive set and include both process and outcomes measures.

- **Stroke measures**—These measures have not been endorsed by the NQF nor adopted by the HQA. Although we are interested in examining the possibility of including care for

stroke patients in future years, these measures are not ready for implementation for FY 2010.

- **AHRQ patient safety and quality indicators**—The HQA has adopted three of the nine AHRQ measures proposed by CMS, including postoperative wound dehiscence, accidental puncture or laceration and abdominal aortic aneurysm mortality rate. We believe these measures are appropriate for public reporting, although significant infrastructure challenges, outlined below, still exist to collect and transmit administrative data on patients of all payers. The other AHRQ measures may have value to hospitals for quality improvement purposes, but in their current format they lack the sensitivity and specificity required for use as comparative, publicly reported measures. Because they are derived from administrative data, they are less sensitive than measures derived from clinical chart abstraction at identifying relevant patients and excluding other patients. Some of the AHRQ indicators have very high false positive rates, meaning that they indicated potential problems, but further investigation showed the care was adequate and the indicator was wrong. To be considered for HQA adoption, and therefore be ready for implementation in the pay-for-reporting program, these measures would need extensive field-testing and respecification.

  CMS proposes that hospitals submit to the CMS data warehouse all-payer claims data to calculate these measures. However, CMS does not describe how this would be accomplished, and it is unclear how this could be done. The Joint Commission data vendors currently collect and submit most of the clinical data for the pay-for-reporting program. However, the vendors do not have the capability to process administrative data in a similar fashion. The data vendors have not been asked if they have the capacity to take on this task, nor has a contract been let to modify the CMS Abstraction & Reporting Tool (CART) to collect these additional data. We are unsure whether CMS expects the data vendors to develop these capabilities or whether a transmission mechanism would be built into the CART tool or another system. Thus far, the CART tool has been under-resourced and has been unable to keep pace with reporting demands. As an alternative means of transmission, CMS also proposes that other entities that collect data for the AHRQ measures, such as state agencies or state hospital associations, could transmit the data directly to CMS, thereby relieving hospitals of the task of submitting the same data to multiple different entities. Again, it is not clear how this would work or who would bear the costs for putting the data in the right format, running edits to check data accuracy and otherwise cleaning the data. There currently is no infrastructure to allow for the transmission of this type of information between outside entities and the CMS data warehouse. It is unclear how CMS would propose to build such an infrastructure.

  It also is unknown how CMS would propose to validate the administrative claims data. All data posted for public display on the *Hospital Compare* Web site should be validated to ensure its accuracy. Data for measures similar to the AHRQ measures have never been collected or validated before. We urge CMS to clarify how it would validate the data for these measures.

We also have serious concerns about the security and privacy of protected information that would have to be sent in such a transaction. CMS would need to ensure that a secure and protected infrastructure is in place and that it has been thoroughly tested prior to use.

It is not clear what patients that are not insured by a government payer would think about the Department of Health and Human Services (HHS) and its contractors having access to the sensitive information that is contained in their billing files. With the quality data, Congress enabled CMS to establish a data warehouse through which individual patient data is processed, and CMS is given aggregate information only. The proposed rule does not clearly delineate how the equally sensitive billing information would be collected so that patient privacy would be protected. If the data go directly to CMS, would they be available through a *Freedom of Information Act* request or other means? How are they to be protected to preserve patient privacy?

- **Cardiac surgery measures from the Society of Thoracic Surgeons (STS) registry**—The STS cardiac surgery measures have been endorsed by the NQF, but they have not been adopted by the HQA. They should not be included for hospital reporting for FY 2010. The STS measures were developed for the purposes of quality improvement and patient safety. They were not developed for the purposes of public reporting or to encourage transparency and accountability. Therefore, they should not be used for public reporting until they are tested further to ensure the validity of the results of the comparisons between hospitals. Other testing should be conducted to determine whether these measures resonate with the public and whether patients find value in the data and can understand the importance of the measures.

  We are very concerned that one of the measures, "participation in systematic database for cardiac surgery" could be viewed as serving the financial interests of a third-party organization. To participate in the STS registry, hospitals must pay a fee to STS and use an STS data vendor. Participation in the program is costly. It is inappropriate for CMS to institute a financial incentive through the Medicare pay-for-reporting program that would require hospitals to pay money to STS.

  CMS recognizes that hospitals not currently participating in the STS program would need to submit their data directly to CMS; however, the agency does not specify how this would occur. For those hospitals that participate in the STS registry, CMS states that an arrangement would be made for STS to directly submit the data to CMS. It also is unclear how this would work. For the CMS data warehouse to accept the data, all of the data elements would need to be specified in the same manner as the data elements for the existing measures. For example, for the current heart attack measure of receiving a beta-blocker at discharge, a patient that receives a beta-blocker is represented in the CMS dataset with a coded value of "E." A patient who is eligible to receive the beta-blocker, but did not receive it, is coded with a "D." The STS measure set also contains a beta-blocker at discharge measure. However, patients who received and who did not receive a beta-blocker may be coded in the STS database with values of "Yes"/"No" or "Y"/"N" or "1"/"0," or any combination of possible values. To bring the STS data into the CMS data warehouse, the differences in the specifications of the data elements would have to be

eliminated. CMS makes no mention in the proposed rule of how this would occur, and the agency does not estimate the time and resources required to make it happen.

Similar to the AHRQ measures, CMS also does not address how the security and privacy of the data would be ensured during a data transfer from STS, and the agency does not provide any information on how the data would be validated to meet the same standards as the other pay-for-reporting measures.

The HQA recently adopted several other measures that CMS did not propose to include for FY 2010. In particular, the HQA has adopted two measures of infection rates: surgical site infection and central line catheter-associated blood stream infection. The HQA believes that these measures are ready for public reporting. They have been thoroughly specified, are currently used in other reporting initiatives, are salient to consumers and hold important information that hospitals can use for their quality improvement programs. CMS lists both of these measures as possible measures for FY 2011 or beyond; however, we believe they are ready for inclusion in the pay-for-reporting program now. **We urge CMS to reconsider implementing them for FY 2010.** In addition, the HQA has adopted measures on the care provided in pediatric intensive care units. The quality measures for pediatric populations, as well as maternity patients and other patient populations not currently represented by the selected measures, should be supported for collection, validation and posting by CMS. As appropriate and fitting with the identified national goals, we urge CMS to take a broader view of the patient populations represented by the measures.

In summary, we support the addition of the following 12 measures that have been adopted by HQA for use in the pay-for-reporting program:

- Surgical site infection rate.
- Central line catheter-associated blood stream infection rate.
- Perioperative beta-blockers for surgical patients.
- Six measures of venous thromboembolism care.
- Three AHRQ patient safety and quality indicators: postoperative wound dehiscence, accidental puncture or laceration and abdominal aortic aneurysm mortality rate.

Program procedures. CMS proposes to allow hospitals that have fewer than five heart attack, heart failure, pneumonia or surgical care patients in a calendar quarter to not submit quality measures data for those patients beginning in FY 2010. Hospitals that have fewer than five HCAHPS-eligible patients in any month will not be required to submit HCAHPS surveys for that month. VIRTUA HEALTH SYSTEM supports this approach as a sensible way to reduce the reporting burden on hospitals with a very small number of cases; however, we believe hospitals should always be able to voluntarily report on quality measures if they want to do so.

For the first time, CMS proposes to use staggered start dates and data submission time frames for the measures in the pay-for-reporting program. We believe this proposal would add unnecessary confusion and additional complexity to an already complicated system. CMS proposes four different start dates, from January 2009 to October 2009, for the group of new measures and does not specify when reporting would begin for the readmission measures. Some of these start dates

are delayed because the specifications for the measures and the data collection and transmission infrastructure will not be ready for hospitals to begin collecting data with January 2009 discharges. This is a clear acknowledgement by CMS that not all of these measures are ready for implementation in FY 2009 for the FY 2010 annual payment update. For example, CMS proposes that hospitals begin data collection on the AHRQ measures with discharges beginning in October 2009 and that the first quarter of data would be due by April 2010. Both of these dates are in FY 2010. This should be proposed and discussed in next year's rule; it is not relevant now, as CMS is not ready to implement data collection for these measures in this fiscal year.

CMS also proposes to stagger the data submission time frames for the new measures. Currently, hospitals must submit the data for all measures within four and a half months of the close of the reporting quarter. CMS proposes a similar time frame for the surgical care, nursing sensitive, venous thromboembolism and stroke measures, but proposes that the AHRQ and STS cardiac measures be submitted within four months of the close of the quarter. We believe that the staggered submission dates are unnecessary and increase the potential for data submission errors to be made. **We urge CMS to adopt one, consistent submission time frame of four and a half months for all pay-for-reporting measures.**

Using alternative data sources. In the proposed rule, CMS seeks comments on what alternative data sources for quality measures could be used in place of chart abstracted data. CMS lists the Continuity Assessment Record & Evaluation (CARE) tool, electronic laboratory test results and clinical data registries as examples of alternative data sources. We believe this is a misguided discussion. Quality measures should not be selected for the pay-for-reporting program simply because there is a readily available data source that can provide information on a particular area of care. Measures should be selected solely on their merit, for their importance, validity and relevance.

In reference to the CARE tool, we believe that it is too early to judge whether the tool may be of value for quality measurement and public reporting purposes. The demonstration project with the CARE tool is in its very beginning stages. We do not know how successfully hospitals can implement the tool, much less whether it has any value for quality measurement purposes.

Infrastructure problems. Recently, CMS has experienced multiple problems with the quality reporting data infrastructure. There have been delays in data submission and reporting timelines. The data warehouse has, at times, lacked the capacity to receive data and has been unable to track the data it has received. There has been inadequate communication to hospitals and their data vendors on many steps of the process. For example, some hospitals have received data validation reports for other organizations. In regular practice, hospitals receive notification only two to three days before a reporting period deadline that they are "missing" one patient case and are in jeopardy of losing their annual payment update. On multiple occasions, the data warehouse had to reprocess files due to programming errors and did not confirm to hospitals whether their cases were accepted during the re-processing or whether they needed to be resubmitted.

We were disappointed that CMS did not discuss these challenges in the proposed rule, nor did the agency ask for comment on how the process could be improved. In the proposed rule, there was no indication by CMS that more resources would be devoted to improving the infrastructure and increasing its capacity. Although CMS proposed adding 43 new quality measures, it did not discuss how this would be managed by a system that is barely able to meet its current demands. **We urge CMS to devote more resources to the data infrastructure and to seek comment through the regulatory process for what changes should be made most urgently.**

Measure maintenance. VIRTUA HEALTH SYSTEM believes it is critical that the measures included in the pay-for-reporting program represent best clinical practice. Therefore, we are pleased that CMS recognizes the need to retire measures if they are no longer relevant or important in distinguishing opportunities to improve care. We agree that the pneumonia oxygenation assessment measure may no longer be necessary for reporting, and we concur with its retirement. However, as the method used to retire or replace measures for the pay-for-reporting program is developed and refined, we urge CMS to include hospitals, data vendors, other stakeholders and the public in the process.

All changes to existing measures should be made through the regulatory process, which allows for public comment. No changes should be made to existing measures through a sub-regulatory process as CMS suggests in the proposed rule. We understand that CMS is planning to respecify the pneumococcal and influenza vaccination measures without consulting the HQA or seeking public input. This is unacceptable. At times, it may be necessary to temporarily suspend measure reporting due to a change in science or an implementation issue, such as with past influenza vaccine shortages. **However, all permanent changes to revise existing measures must be made through the regulatory process to allow for public input.**

Data resubmission, validation and appeals. The proposed rule does not address the issue of data resubmission when a hospital or its vendor becomes aware of an error in the data that was sent for posting on *Hospital Compare*. **VIRTUA HEALTH SYSTEM urges immediate adoption of an effective mechanism for allowing hospitals and their vendors to resubmit quality measure data if they discover an error**. The point of public reporting is to put accurate and useful information into the hands of the public, and this is facilitated by allowing known mistakes to be corrected. CMS recognized this in its value-based purchasing report to Congress. There is no reason why this should not be implemented now in the pay-for-reporting program.

In addition, improvements must be made to the current validation process. Many hospitals have been notified that there have been problems validating the data they submitted. In several instances, these validation problems have been due to inconsistencies in the definitions of variables used by CMS's contractors who are reabstracting patient-level data and comparing it to the data submitted by the hospitals. In other instances, a mismatch between single data elements unrelated to the quality of care provided by a hospital, such as the patient's birth date, have caused hospitals to fail validation. The reabstraction of five charts per quarter for each hospital is insufficient to ensure the reliability of the data. A more resilient and less resource-intensive method of validation is needed. We believe that the ideas for reforming the data validation process that were put forward by CMS in its value-based purchasing report to Congress hold promise as an improved approach toward data validation. We were disappointed that CMS did

not propose similar changes for the pay-for-reporting program in the proposed rule. **We urge CMS to propose an alternative data validation process for the pay-for-reporting program as soon as possible.**

A hospital should have the opportunity to file an appeal if it believes it wrongly failed the data validation process. The appeals process should be straightforward, transparent and timely. **Hospitals should have clear guidance on how to submit their appeals, and CMS should provide timely appeals decisions.** In the proposed rule, CMS states that it will provide hospitals with a decision within 60 to 90 days of their appeal. This delay is burdensome and unnecessary. Because CMS decreases a hospital's payments during the appeals process, it may cause unnecessary cash flow problems for hospitals whose validation results are later overturned. This could be particularly harmful for hospitals serving large numbers of uninsured patients. In 2008, CMS was able to process all appeals within 60 days. **There is no reason why this timeline must be expanded to 90 days for FY 2009.** In its value-based purchasing report to Congress, CMS outlines an appeals process through which hospitals that initially fail validation will not receive lower payment while their appeals are ongoing. Only after a final decision is reached would any payment adjustments be made. This logical process should be established now in the pay-for-reporting program.

DRGs: HOSPITAL-ACQUIRED CONDITIONS

The DRA required CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a complication or comorbidity (CC) DRG. The conditions must be either high-cost or high-volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of evidence-based guidelines. The DRA mandates that for discharges occurring on or after October 1, 2008, the presence of one or more of these preventable conditions would not lead to the patient being assigned to a higher-paying DRG.

In the FY 2008 inpatient PPS final rule, CMS adopted eight conditions for which it would no longer pay a higher DRG rate beginning in FY 2009 if the conditions were not present on admission. Those eight conditions were:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility;
- Pressure ulcers;
- Falls and trauma;
- Catheter-associated urinary tract infections;
- Vascular catheter-associated infections; and
- Surgical site infection—mediastinitis after coronary artery bypass surgery.

This year, CMS proposes to expand the list to include nine additional conditions when the payment policy takes effect on October 1. The nine conditions are:

- Surgical site infections following elective procedures;
- Legionnaires' Disease;
- Glycemic control;
- Iatrogenic pneumothorax;
- Delirium;
- Ventilator-associated pneumonia;
- Deep-vein thrombosis/pulmonary embolism;
- *Staphylococcus aureus* septicemia; and
- *Clostridium difficile*-associated disease.

Most of the conditions selected by CMS do not fulfill the statutory requirement that they be reasonably preventable through the application of evidence-based guidelines. **To be reasonably preventable, there must be solid evidence, published in peer-reviewed literature, that by engaging in a certain set of practices, clinicians can reduce the occurrence of an event to zero, or near zero, among a typically broad and diverse patient population.** Currently available evidence indicates that for many conditions, even when all appropriate care is given, we do not yet know how to reduce the rates of these conditions to zero or near zero. Some patients, particularly high-risk individuals, may still develop the conditions on the list.

Where guidelines and proven strategies exist, hospitals strive to ensure that serious, adverse events do not occur. While we endeavor to do the best for patients through the use of sophisticated systems, information technology and care protocols, human error can and does occur. When serious events occur, hospitals believe that information about the error should be quickly and openly communicated to patients and their families, and that the purchasers of those health care services—patients, insurers or employers—should not be billed for that care. The New Jersey Hospital Association has asked all hospitals to review their current billing policies and practices and ensure they reflect their organizations' internal policies about foregoing payment for costs associated with care made necessary due to a preventable medical error that occurred during the course of care in that organization.

CMS could provide leadership to the hospital field in identifying where solid evidence exists that certain conditions can be prevented and by helping hospitals focus on the efforts they can take to prevent them. However, the implementation of a list of 17 conditions does not provide that leadership. A recent report by the Government Accountability Office found that the HHS is lacking the leadership to prioritize recommended practices and help guide implementation of evidence-based practices in hospitals. This proposed list of conditions is another example of a disjointed approach to quality improvement. The inclusion of some of these conditions on the list leads us to believe that CMS did not obtain the necessary clinical and expert input on what conditions may be appropriate for this policy.

We recommend that CMS develop an advisory panel of clinicians and scientists to provide the agency with guidance on which conditions are appropriate for inclusion under this policy. The advisory panel should include both academic researchers and clinicians who are actively

providing patient care in the inpatient hospital setting. The role of the advisory panel should be to review the scientific evidence on the preventability of the conditions on the list and help CMS more specifically define the particular patient populations to whom the payment policy should be applied. For example, there is solid research showing the benefits of controlling blood glucose levels among certain surgery patients. However, for patients with many other conditions, there is no established scientific evidence around this practice. If CMS were to choose to include glucose control as a condition, it would be more reasonable to apply the payment policy only for those patients where there is solid evidence that controlling blood glucose levels is a best practice. The technical advisory panel also should review the experiences and results from those states that have already implemented present-on-admission coding or adverse-event reporting. States such as California and Minnesota have experience implementing policies related to CMS's hospital-acquired conditions policy. We recommend that CMS examine the outcomes from these states and the lessons learned in refining its own policy.

For this policy to be implemented fairly, some adjustment must be made to account for the differences in patient populations among hospitals. Without using a risk-adjustment methodology, hospitals that admit a higher proportion of sicker patients, who are more at risk for some of the conditions, will unfairly bear a larger financial penalty. Additionally, certain high-risk patient populations should almost always be excluded from this policy. Trauma patients and patients near the end of life receiving palliative care are examples of high-risk patient populations that should not be included in this payment policy for most of the proposed conditions.

Additionally, we believe that hospitals will face significant challenges in diagnosing these conditions accurately on admission and coding for them at that time. Coding accuracy can only be achieved when physicians have been educated about the need to carefully identify and record, in an easily interpretable manner, whether these conditions are present on admission. To date, CMS has done little to initiate such an education process.

Conditions to include for FY 2009. VIRTUA HEALTH SYSTEM believes that four of these conditions are appropriate to include for FY 2009. These include three serious, adverse events—object left in during surgery, air embolism and blood incompatibility—and vascular catheter-associated infections. Because these conditions are identified by discrete ICD-9 codes, they can be coded by hospitals. More importantly, these are events that can cause great harm to patients and for which there are known methods of prevention. However, VIRTUA HEALTH SYSTEM requests that CMS provide technical guidance on how it would address certain situations of retained foreign objects. In some circumstances, it may be in the best interest of the patient not to remove the object. Leaving a patient under anesthesia for a prolonged period of time and displacing internal organs in a search for a microscopic surgical object left in the body may be more harmful than leaving the object inside the patient and completing a surgery in an expedited fashion. We suggest that CMS clearly specify that the policy applies to an *unintended* retention of a foreign object, to allow physicians to exercise their clinical judgment regarding the relative risk of leaving an object in versus removing it. Additionally, we would appreciate guidance on how CMS would address a situation in which a foreign object left in the body after surgery is found by the same hospital, but in a different fiscal year, or by another hospital.

Conditions not ready for inclusion for FY 2009. The other conditions, including those adopted in the FY 2008 inpatient PPS final rule and those proposed in the FY 2009 proposed rule, should not be implemented for FY 2009.

Our specific concerns with each of the conditions follows.

- **Pressure ulcers**—We do not believe that pressure ulcers should be included in this policy because they do not meet the definition of "reasonably preventable." Certain patients, including those at the end of life, may be exceptionally prone to developing pressure ulcers, despite receiving appropriate care. The best method of preventing pressure sores is to turn the patients. But patients who have suffered trauma or have underlying conditions that make turning inadvisable are at greater risk of pressure ulcers. Some patients have fragile skin that puts them at greater risk. There also is evidence of an increased risk of pressure ulcer reoccurrence after a patient has had at least one stage IV ulcer. Other patients may be at risk for a pressure ulcer, but it may be more harmful to the patients' overall health to move them than to take the risk of a pressure ulcer developing. For example, an obese patient with a serious spinal injury may be at a high risk to develop a pressure ulcer, but due to the nature of the spine injury, it is safer for the patient to remain in one position.

  In addition, it may not always be possible, or in the best interest of the patient, to examine the patient for pressure ulcers when they arrive at the hospital. For example, a patient who arrives in coronary distress, with traumatic injury or with any other life- or function-threatening condition requires immediate care for their urgent condition, which should not be delayed by a search for skin breakdowns.

  In the proposed rule, CMS has clarified that, with the development of new ICD-9 codes that capture the staging of pressure ulcers, hospitals must code both the staging and the site of a pressure ulcer. CMS has proposed, however, to remove the CC and major complication or comorbidity (MCC) classifications from the current pressure ulcer codes that show the site of the ulcer (ICD-9-CM codes 707.00 through 707.09). Therefore, hospitals will only be able to indicate CC/MCC classifications if they include one of the new codes indicating the stage of the ulcer. Further, only stage III and stage IV pressure ulcers would be included under the hospital-acquired conditions policy and have these CC/MCC classifications.

  We recommend that CMS collect sufficient data before implementing the proposal to remove the CC/MCC classifications from the current pressure ulcer codes that show the site of the ulcer. Hospitals will need time to learn to correctly use the new staging codes and adjust their processes to ensure these stages are documented in their records. Additionally, we believe that CMS's proposal that only stage III and stage IV pressure ulcers would have CC/MCC designations is inconsistent with CMS's long-standing tradition of treating new codes in the same manner as the predecessor codes. CMS has traditionally not moved conditions across DRGs, or changed the CC/MCC status of a code, until sufficient claims data are available to determine the impact on hospital resources. Therefore, we recommend that CMS recognize the codes for stage II pressure

ulcers (707.22) and unstageable pressure ulcers (707.25) as a CC and stage III and IV pressure ulcers as an MCC until sufficient claims data are available to determine the impact on hospital resources.

- **Falls and trauma**—This condition should not be included in this policy because it does not meet the definition of reasonably preventable. Not all patient falls are the result of a mistake by the hospital, and not all falls can be prevented by the hospital. In some cases, even though the hospital can provide the best care, come swiftly to the patient's assistance when the patient calls for help, and minimize the use of restraints, the patient may get out of bed on her own and suffer from a fall.

- **Catheter-associated urinary tract infections**—This condition should not be included because prevention guidelines for catheter-associated urinary tract infections are still debated by clinicians. Additionally, many clinicians believe that urinary tract infections may not be preventable after several days of catheter placement, and certain patients, such as trauma patients, may need catheters for extended periods of time. Clinicians may not always know upon admission if a patient has a bladder infection. The only method to verify present-on-admission status would be to institute universal screening upon admission, which would be unnecessarily burdensome to patients, costly to hospitals, and would not necessarily identify those patients with infections.

- **Surgical site infection—mediastinitis after coronary artery bypass graft**—Although mediastinitis should not occur after the surgeries of uncomplicated patients, patients with comorbid conditions, such as diabetes or obesity, will be at higher risk for any infections after surgery, and not all infections may be preventable. Patients with serious co-morbidities should be excluded from the patient population for this condition.

- **Surgical site infections following elective procedures**—We agree that there are evidence-based practices that should prevent most surgical site infections. However, several of the surgeries selected for inclusion under this policy do not seem appropriate. Varicose vein ligation and stripping is typically performed as an outpatient procedure. The other surgeries are typically short-stay procedures. Any infections occurring post surgery would likely not be identified during the initial hospitalization, but would cause a patient to seek medical care after discharge. These events would not be captured under CMS's hospital-acquired conditions policy. Those patients undergoing a laparoscopic gastric bypass are obese and, therefore, are already at higher risk for a surgical site infection or other complication.

  Of these surgeries, only the total knee replacement surgery was included in the Surgical Care Improvement Project (SCIP). We would support the inclusion of this condition in the future as long as the payment penalty was applied only in those instances when not all of the recommended perioperative surgical processes were carried out. This would require CMS to implement some level of medical record or case review in deciding whether or not to lower the hospital's payment rate.

However, we note that almost all knee replacement surgeries fall into three DRGs that are solely dependent on the presence or absence of an MCC: "Major joint replacement or reattachment of lower extremity without MCC" (470); "Major joint replacement or reattachment of lower extremity with MCC" (469) and "Bilateral or multiple major joint procedures of lower extremity without MCC" (462). The codes proposed by CMS to identify hospital-acquired conditions for knee replacement surgery include only CCs, "Infection and inflammatory reaction due to internal joint prosthesis" (996.66) and "Other postoperative infection" (998.59), and no MCCs. Thus, knee replacement surgery patients' DRG assignments will be the same whether or not these selected hospital-acquired condition codes are present.

- **Legionnaires' Disease**—Similar to the other infections included on this list, a patient may come into the hospital already colonized with Legionnaires' Disease. There is no way to be sure whether the condition is present on admission other than to screen all patients, which would be unnecessary and costly. There are no clinical differences between Legionnaires' Disease acquired outside of the hospital setting and Legionnaires' Disease acquired within the hospital, so determining the site of the infection would be technically impossible.

  There is no consensus opinion among experts on how to prevent Legionnaires' Disease due to the lack of evidence-based recommendations, the questionable validity of environmental monitoring, and remaining questions on how to perform active disinfection of a water system. The Centers for Disease Control and Prevention (CDC) does not recommend routine environmental screening in hospitals for the bacteria that cause Legionnaires' Disease. The primary reason against routine testing is that the relationship between water culture results and the risk to patients of contracting Legionnaires' Disease remains undefined. The bacteria that cause Legionnaires' Disease can be present in the water systems of buildings without being associated with known cases of the disease. Thus, conducting environmental surveillance, which the CDC does not recommend, would obligate hospitals to initiate water-decontamination programs if the bacteria are identified, even if there have been no identified case of Legionnaires' Disease.

- **Glycemic control**—CMS also selects "extreme aberrations in glycemic control" as a condition. However, the agency does not provide a clinical definition of "extreme aberrations." Clinicians we spoke with were unable to determine exactly what CMS meant by this phrase. While there is scientific evidence to suggest that controlling blood glucose levels can prevent infections for surgery patients, tightly controlling blood glucose levels for all patients has not been scientifically validated. In fact, under certain conditions, blood glucose levels that are too tightly controlled could put the patient in danger of hypoglycemia, which is at least as dangerous as hyperglycemia. For example, because blood glucose levels are responsive to hormones, if a patient is experiencing anxiety before surgery, the patient's blood glucose level may increase. The clinician may try to control the elevated blood glucose level and bring it down during the perioperative period. However, post surgery, when the patient is no longer experiencing stress, the blood glucose level may naturally decrease. Without careful monitoring, the patient

could become hypoglycemic simply because the blood glucose level had been previously controlled.

Some diabetics have poorly controlled blood sugar levels that are not a result of any care the hospital did or did not provide. If a diabetic patient with poorly controlled blood glucose levels is admitted to the hospital for immediate, necessary surgery, the hospital may have to take the risk that the patient's blood glucose levels will become even more elevated during the surgery. Balancing the risks and benefits for each treatment for each patient is a fact of providing care. Just as there is no one-size-fits-all way to practice medicine for all patients, this condition cannot be applied to all patients under this policy.

- **Iatrogenic pneumothorax**—Iatrogenic pneumothorax is not reasonably preventable. In emergency situations, it may be necessary to place a central line in an access point, such as the subclavian or jugular veins, with a higher risk of pneumothorax. However, if these sites are the only access points available to the clinician to place the central line, they must be used. Additionally, there is anatomical variation among all patients that makes it possible that a pneumothorax could happen during a medical procedure regardless of the skill with which the procedure is performed.

- **Delirium**—There is no clear clinical definition of delirium, particularly as a patient comes into or out of a state of delirium; therefore, its inclusion on the list is problematic. Further, as CMS acknowledges in the proposed rule, evidence-based practices may only prevent 30 to 40 percent of cases, meaning most cases cannot be prevented. This does not meet the definition of reasonably preventable.

  Delirium is an unfortunate side effect that can occur for a number of reasons, most of which are not within the control of the hospital or the result of a mistake made by the hospital. For example, many patients with Alzheimer's disease or dementia experience delirium when they are placed in a new, unfamiliar environment, such as a hospital. Simply changing the environment from one the patient was accustomed to can induce the delirium. While this symptom is very difficult for the patient's family to cope with, the symptoms almost always subside and disappear completely once the patient is adjusted to the new environment or returned to her usual residence. Many physicians believe that it would do no good, and could be potentially harmful, to over-medicate patients in this condition in an attempt to reverse the delirium. In another example, it is sometimes necessary to withdraw patients from certain medications prior to surgery. This may cause temporary delirium. However, the temporary delirium is less harmful to the patient than completing the surgery while the patient has the potentially harmful drug in his system.

- **Ventilator-associated pneumonia**—Certain patients, such as trauma or immunocompromised patients, may be at a high risk for developing ventilator-associated pneumonia. For some patients, their medical conditions make it more difficult or impossible to implement all evidence-based practices. For example, trauma patients with certain injuries might not be able to have the head of the bed elevated as suggested in some guidelines. CMS states in the proposed rule that the scientific evidence suggests

that 60 to 80 percent of ventilator-associated pneumonia cases *cannot* be prevented, which again, does not meet the definition of reasonably preventable.

We also are concerned over the lack of standardized clinical definitions or criteria for ventilator-associated pneumonia. The fact that the definition is open to interpretation means that clinicians may diagnose it differently in similar patients. These differences would be reflected in the medical record documentation and might unfairly penalize those organizations that more liberally diagnose ventilator-associated pneumonia. Hospital coders will need detailed instructions on the assignment of the newly created code 997.31. The *Official Guidelines for Coding and Reporting* requires that code assignment for postprocedural complications be based on the provider's documentation of the relationship between the infection and the procedure. We believe that the same should hold true for all complication codes, including the new ventilator-associated pneumonia. Coders are not allowed to code on the basis of abnormal lab findings alone, nor are they allowed to interpret clinical findings or diagnose patients.

Therefore, we are concerned that the codes listed in the proposed rule "to identify cases in current Medicare data" for ventilator-associated pneumonia seem to imply that the mere fact that a patient is on a ventilator (code 96.70-96.72) and has a pneumonia code would constitute ventilator-associated pneumonia. Some of the pneumonia codes included would not be routinely associated with a ventilator, such as 073.0 (Ornithosis with pneumonia) or 136.3 (Pneumocystosis). Code 073.0 refers to pneumonia that results from an infectious disease that is usually transmitted to humans from birds. Code 136.3 refers to pneumonia due to a fungal organism *Pneumocystis carinii* (now renamed *Pneumocystis jiroveci*), that is common in the environment and does not cause illness in healthy people, but can cause a lung infection in people with a weakened immune system due to conditions such as cancer, HIV or transplant status.

- **Deep-vein thrombosis/pulmonary embolism**—This condition is similar to pressure ulcers in that there may be certain trauma patients who are at risk for developing a clot, but their condition is such that they cannot be moved from one stationary position. Additionally, patients with clotting disorders or who are in a hypercoagulated state may be more likely to develop a blood clot that could not be prevented even with the best of care. Blood clots can be difficult to detect on admission if the typical symptoms of swelling and inflammation are not yet apparent, even though the clot has already formed.

- S***taphylococcus aureus*** **septicemia**—Accurately identifying the presence of *staphylococcus aureus* septicemia on admission will be a challenge. Patients may be admitted to the hospital with a *staphylococcus aureus* infection of a limited location, such as pneumonia, urinary tract infection or skin infection. Subsequent development of *staphylococcus aureus* septicemia may be the result of the localized infection and not a hospital-acquired condition. Additionally, the proliferation of changes in coding guidelines for sepsis in recent years present further challenges to hospital coding personnel to accurately capture present-on-admission status. Finally, there is still some debate among clinicians regarding the prevention guidelines for *staphylococcus aureus* septicemia.

We believe the category of *staphylococcus aureus* septicemia is simply too large and varied to be able to say with confidence that the infections were reasonably preventable. We urge CMS to narrow this category to include only patients for whom it is reasonably clear that the hospital was the source of the infection and that it could have reasonably been prevented.

We disagree with the range of codes identified for *staphylococcus aureus* septicemia. The only code needed to represent this condition is 038.11, *staphylococcus aureus* septicemia. We disagree with all other codes listed under this condition in the proposed rule because they do not uniquely identify this condition, one of CMS's criteria for selection of a hospital-acquired condition. For example, 995.91 and 995.92, respectively, identify sepsis and severe sepsis resulting from any infectious condition, not just *staphylococcus aureus*. Code 998.59, other postoperative infection, is not for septicemia and is not specific to *staphylococcus aureus*. In fact, code 998.59 does not indicate a systemic infection, as it could be applicable to a localized infection such as a postoperative abscess. In addition, subcategory 999.3, other infection, includes code 999.31 (infection due to central venous catheter, which has already been selected as a hospital-acquired condition) and 999.39 (infection following other infusion, injection, transfusion, or vaccination).

- ***Clostridium difficile*-associated disease (CDAD)** —CDAD can be an unfortunate side effect from the use of antibiotics among individuals whose health is compromised. However, when patients are put on strong antibiotics it is because they are fighting a serious infection. That infection is likely to be far more dangerous to the patient's overall health than the uncomfortable side effects of CDAD. In another example, a hospital may give a surgical patient an antibiotic during the perioperative period as is recommended by the SCIP and the quality reporting measures. Such a patient may experience CDAD. Thus, following one set of evidence-based guidelines could result in a side effect that causes a hospital to be penalized under the hospital-acquired conditions policy.

  Many individuals are already colonized with CDAD. Therefore, it is not acquired in the hospital nor the result of a mistake made by the hospital. Some clinicians have pointed out that clearly distinguishing community-acquired CDAD from healthcare-associated CDAD can be difficult. We do not believe all patients entering the hospital should be tested on admission to determine if they are colonized with CDAD. Nor do we believe physicians should withhold prescribing antibiotics to patients who need them because there is a chance the patient may experience CDAD. We do not believe CDAD is reasonably preventable or appropriate for inclusion on this list.

In the proposed rule, CMS also discusses the public health concerns of Methicillin-resistant *staphylococcus aureus* (MRSA), but it proposes not to include MRSA as a hospital-acquired condition for payment purposes under the inpatient PPS. We support this decision because of the inconclusive evidence base on the preventability of MRSA, and we agree with CMS that the presence of MRSA as a colonizing bacterium does not always result in harm to the patient.

Payment changes based on present-on-admission coding. The payment changes for hospital-acquired conditions will apply only when the selected conditions are the only CCs or MCCs present on a claim. Under this policy, CMS would not make higher payments for the selected conditions if they are coded as not present on admission or if the medical record documentation is insufficient to determine whether the condition was present on admission. In other words, CMS would not make a higher payment if the condition is coded on the claim with an "N" (not present on admission) or a "U" (medical record documentation is insufficient). CMS proposes to not pay a higher payment amount when the medical record documentation is insufficient because it believes this will foster better medical record documentation.

The reporting of present-on-admission indicators is still new, and hospitals continue to learn how to apply them, as well as educate their physicians on the required documentation without which present-on-admission reporting is impossible. We urge CMS not to implement the proposal not to pay for hospital-acquired conditions coded with the "U" indicator. According to the *Official Guidelines for Coding and Reporting*, the "U" reporting option "should not be routinely assigned and used only in very limited circumstances." Coders are encouraged to query the providers when the documentation is unclear. We agree that there should be limited circumstances when "U" is reported. However, those circumstances are more likely to be due to lack of physician availability or lack of physician response to a hospital query for more specific information. It is important to distinguish these circumstances from those where the physician is not able to provide more specific present-on-admission information (even after a hospital query) because the patient expired or was transferred before a clinical evaluation could be completed to determine whether a condition was present on admission or not. We believe such situations should be reported with a present-on-admission indicator of "W" or clinically undetermined. We recommend that CMS analyze the reporting of option "U" and determine whether there is a problem with over-reporting before a decision is made not to pay for CC/MCC reported with a "U."

Unintended consequences. VIRTUA HEALTH SYSTEM encourages CMS to consider the unintended consequences that might arise from implementing the hospital-acquired conditions policy. Trying to accurately code for some of these conditions that are present on admission may lead to excessive testing for patients entering the hospital. The necessity to complete diagnostic tests before a patient is admitted to confirm whether a condition was present on admission could lead to delayed admissions for some patients and disrupt efficient patient flow.

Other technical clarifications. VIRTUA HEALTH SYSTEM would like clarification from CMS on how hospitals may appeal a CMS decision that a particular patient falls under the hospital-acquired conditions policy and is not eligible for a higher DRG payment. A process for hospitals to appeal a decision about specific patient cases is vitally necessary to ensure accountability.

Enhancement and future issues. CMS asks for comment on several potential future refinements to this policy. In particular, CMS asks for comments on whether rates should be collected to measure the incidence of these conditions and whether information learned from the present-on-admission coding could be used for quality improvement purposes. CMS also asks for comment on whether the adoption of ICD-10 codes could facilitate more accurate identification of hospital-acquired conditions.

Information on the incidence rates of these conditions learned through present-on-admission coding should not be publicly reported. All information used for public reporting should continue to proceed through the established mechanism. Measures must first be endorsed by the NQF and then adopted by the HQA. Measures that fulfill those criteria may then be considered for inclusion by CMS in the pay-for-reporting program. For example, the HQA has adopted measures of surgical site infection rates and central-line associated bloodstream infection rates. These measures are ready for inclusion in the pay-for-reporting program. A separate reporting site outside of *Hospital Compare* should not be developed, and measures that are not NQF-endorsed and HQA-adopted should never be used.

We encourage CMS to explore how information learned from present-on-admission coding could be used to better understand and prevent certain hospital-acquired conditions. Improving care for patients should be the end goal of this policy. We urge CMS to use the new information available to examine ways that care can be improved.

ICD-10-PCS and ICD-10-CM. We strongly agree with CMS that the adoption of ICD-10 could facilitate more precise identification of hospital-acquired conditions. However, we believe that there may have been a typographical error in referring to ICD-10-PCS (which contains procedure codes), rather than ICD-10-CM in relation to diagnosis codes. We agree that ICD-10 (both diagnosis and procedure codes) are more precise and capture information using more current medical terminology.

The need to replace ICD-9-CM diagnoses and inpatient procedure codes has been under discussion since the early 1990's. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and current medical terminology, and is in critical need of upgrading.

We urge the Secretary to expeditiously undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS. The Department of Health and Human Services (HHS) should take the necessary steps to avoid being unable to create new diagnosis or procedure codes that reflect evolving medical practice and new technology. It is easier to plan for this migration than to respond to the significant problems that will likely result in unreasonable implementation time frames. **VIRTUA HEALTH SYSTEM still believes that the health care field will need a minimum of two years to implement ICD-10-CM and ICD-10-PCS. It is imperative that the rulemaking process starts immediately so as to not jeopardize the two-year implementation time frame required.**

FINANCIAL RELATIONSHIPS BETWEEN HOSPITALS AND PHYSICIANS

CMS for the third time proposes an "information collection request" (ICR) that would require approximately 500 hospitals to report information, supply documents and make certain legal certifications regarding their relationships with physicians. With the exception of an increase in the estimated burden (still greatly understated), the proposal is identical to the one submitted to the Office of Management and Budget in September 2007 and withdrawn in April 2008 in the

face of serious objection to the burden and scope of the request by the AHA and others on behalf of the adversely affected community hospitals.

We again object to the proposed ICR, as it affects community hospitals that would be subject to the intrusive and burdensome demand for information regarding compensation arrangements. CMS's explanation of the purpose and need continues to be insufficient to justify the time, effort and dedication of resources that would be required of community hospitals.

CMS continues to blur the congressional directive in the *Deficit Reduction Act of 2005* (DRA) that CMS "develop a strategic and implementing plan" to address issues of concern to Congress regarding "physician investment in specialty hospitals" with its interest in collecting compensation information from community hospitals. VIRTUA HEALTH SYSTEM supports and encourages CMS to complete the work it started and any additional work that may be needed to meet the DRA mandate. The DRA did not, however, mandate and does not justify the ICR regarding community hospitals' compensation arrangements.

There are two fundamental problems with this proposal and the initiative: the objective is too abstract (evaluate compliance) and the demand for information is, not surprisingly, too sweeping. After two rounds of notice and comment, the third proposal still effectively asks for the maximum amount of information and effort and treats the response as ministerial.

There is no description of a compliance problem that might merit the burden created. Likewise, there is no explanation of how all the information being requested would be used in evaluating compliance. There also is no recognition of the significance of what is being asked. Executive management is required to make certifications regarding the completeness of the submission, compliance with specific provisions of the law and explanations of noncompliance. Yet CMS asserts that the task can largely be handled by administrative staff. The Disclosure of Financial Relationships Report (DFRR) begins with the maximum burden and no articulation of objectives against which the manner and method can be evaluated, and no exploration of a less costly and burdensome approach.

The burden estimate and the CMS description of what a response will require are at odds with current recordkeeping processes in hospitals. Record keeping is predominantly manual, not electronic; documents are decentralized, not centralized; and there is no "self-referral law" filing system required. The number of physicians on staff will affect the number of potential contracts. Having been told that the request will sometimes lead to hundreds of contracts being identified, located, reviewed and copied—manually to the largest extent—CMS offers no explanation of why this is justified. While CMS has increased the estimate of burden in this third proposal, it has made no adjustment in the substance of what it proposes.

Why should a small, medium or large hospital be asked to divert resources to this request? While CMS makes the point that it is proposing a 10 percent sample of hospitals be included in the first stage of the request, it never explains why it needs 100 percent of files, relationships and information.

CMS requests information on nine different categories of compensation arrangements. For those categories most commonly engaged in (e.g., recruitment arrangement), it asks for copies of every contract in effect during a calendar year. Depending on the size of the hospital, documents will be required for hundreds or thousands of contracts. And the number of contracts only begins to describe how many pieces of paper will need to be copied.

Anecdotally, the burden estimates for hospitals include:

- The number of contracts affected can include: 400; 500-600; 800-1,000.
- At least 200 hours will be needed just to identify and assemble all the relevant contracts.
- Three to four weeks will be required to fully respond, assuming no vacations or holidays for involved staff.
- Two to three months to respond with one full-time equivalent employee's time.
- Smaller hospitals will have fewer contracts, with fewer staff to complete the work, and a greater need for outside attorneys or auditor support.
- Hospitals with a fiscal year that is not a calendar year are required to provide documents for two fiscal years, doubling their workload.

Copying the documents will be the last step and the least of what it will take for a hospital to comply. They must identify all the relevant contracts, where they are located and assemble them in a central location. Only then can the kind of review and analysis be completed that will be necessary to answer the specific questions asked and to enable a CEO to make the certification that is required. Some questions require information on arrangements for which a simple review of the agreement will not be sufficient. For example, knowing which specific exception an arrangement relied on when more than one may be applicable will not necessarily be noted in the contract. Only an attorney's review will allow a hospital to determine that information.

Under the current rule, routine mandatory reporting is not required. In fact, it was included in the proposed rule on reporting. And, after hearing from the field that it would be unduly burdensome, CMS made a conscious decision not to use that approach. It also made clear that it was not developing any forms or record-keeping requirements specific to reporting. The DFRR, therefore, would circumvent CMS's own rulemaking decision.

There is nothing in the regulations to support imposition of the broad-based, all-encompassing demand of the DFRR. While CMS reserved the right to make requests on an individual basis, the DFRR is much different. This is a wholesale mandatory request. An individual request would have to be justified on grounds specific to the circumstances of the entity from which the information was requested. The DFRR is not a reasonable exercise of agency discretion and is outside the scope of the current rule, whether judged as a mandatory reporting system or an individual request.

CMS should not proceed with this intrusive, costly and very burdensome demand on community hospitals.

IOWA HOSPITAL ASSOCIATION

July 13, 2008

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS 1390-P
P.O. Box 8011
Baltimore, MD 21244-1850

Ref: CMS—1390-P Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates;

Dear Mr. Weems,

On behalf of Iowa's 35 hospitals reimbursed under the Medicare inpatient Prospective Payment System (PPS), the Iowa Hospital Association (IHA) is pleased to take this opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the FY 2009 inpatient PPS published in the April 30, 2008 *Federal Register*.

IHA is strongly opposed to language included in this proposed rule that would alter the longstanding practice of applying a national budget neutrality adjustment to the rural floor of the wage index and replace it with a state-specific budget neutrality adjustment. Budget neutrality must remain a national policy in accordance with current practice in order to retain balance and symmetry within a complex wage index environment.

The impact of this proposal alone would result in a loss to Iowa's PPS hospitals of more than $500,000 in FY 2009, provides no savings to the Medicare Trust Fund, and negates the benefits Congress intended by applying a rural floor to the wage index.

Since 1999 when the rural floor policy was implemented, CMS has failed to provide a budget neutral adjustment to the payment rates and as a result, PPS hospitals have been underpaid since FY 1999. Responding to IHA's comments in the FY 2008 inpatient PPS final rule CMS acknowledged it had failed to make this adjustment and thus provided a partial year fix for one year of payments. Iowa PPS hospitals are presently engaged in a Medicare group appeal on this very issue. **As a result of CMS' calculation error, Iowa PPS hospitals have lost just under $10 million from FY 2004 through FY 2007.**

In this proposed rule CMS illustrates it continues to undermine this federal payment system by proposing to apply the budget neutrality adjustment for the rural floor at a state level, thereby harming the very states Congress intended this provision to help.

IHA is supportive of meaningful changes to the computation of the Medicare wage index that aligns payments with the efficient delivery of high quality health care that Iowa's hospitals have demonstrated and continue to perfect since the implementation of the Medicare inpatient PPS.

This proposal offers no meaningful changes to the wage index and must be withdrawn.

Thank you for your review and consideration of these comments. If you have questions, please contact me at the Iowa Hospital Association at 515/288-1955.

Sincerely,

Heather D. Hulscher

Heather D. Hulscher
Director, Finance Policy
Iowa Hospital Association

cc: Iowa Congressional Delegation

New Hampshire Hospital Association

June 13, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S. W., Room 445-G
Washington, DC 20201

RE: CMS 1390-P, Medicare Program, Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Rule (Vol. 73, No. 84), April 30, 2008

Dear Mr. Weems:

The New Hampshire Hospital Association (NHHA), on behalf of our 26 member hospitals, appreciates this opportunity to comment on the proposed rule for FFY 2009 for the Inpatient Prospective Payment System (IPPS). Our comments are focused on two central areas: implementation of many of the new hospital quality measures, as well as payment cuts related to the wage index, capital payments and the post-acute care transfer policy. Specifically, NHHA has grave concerns about the proposal for applying the budget neutrality (BN) adjustment for the rural floor (RF) on a state specific (SS) basis and the proposal to increase the wage criteria for attaining geographic reclassification.

Wage Index

- **NHHA opposes changing the Rural Floor Budget Neutrality Adjustment from a national to a state-specific budget neutrality adjustment.**
- **NHHA also opposes increasing the wage comparability threshold for reclassification.**
- **NHHA is equally concerned and opposed to the reclassification on a state-specific basis proposal.**

In the proposed rule, the Centers for Medicare and Medicaid Services (CMS) has made two proposals which affect the Area Wage Index (AWI). These proposals apply the budget neutrality (BN) for the application of the RF on a SS basis and increase the wage comparability threshold for reclassification. The SS RF BN application is contrary to the "pool finding" concept

employed by many of CMS' policies and the change in the reclassification threshold would reduce both the RF and reclassifications. These proposals appear to be poorly developed as there are many implementation issues as well as ancillary questions that arise. Separately, the SS RF BN proposal appears to be fostering the adoption of the separate proposal in the President's budget that would apply the BN adjustment for reclassifications on a SS basis. **We are equally concerned and opposed to the reclassification on a state-specific basis proposal on essentially similar principles.**

I. Background

In FFY 2008, the CMS changed the RF BN calculation in several ways; the method of calculation; the data utilized in the calculation; and the location of the adjustment with the payment system. In making this FFY 2008 change, despite a request for an explanation, the CMS never explained the rationale for that change nor the specific differences between that change and the previous methodology which had been in place for nearly a decade. Thus, the exact method and data related to the FFY 2008 change was never fully disclosed.

In the proposed rule for FFY 2009, the CMS is again proposing to change the RF BN calculation and its effects. For FFY 2009, the CMS would apply the RF BN on a SS basis. While there are varied policy issues that evolve from this proposed change, there are also key substantive data and methodological issues that the agency has not disclosed or described which are critical to the ability to render meaningful comment.

Our comments regarding the proposed SS RF BN change and the proposed change to the reclassification criteria follow.

II. Conceptual and Policy Problems with the SS RF BN Proposal

- The Medicare program has long been a national program, reverting to a state-by-state formula is a significant and potentially troublesome precedent

  Despite the fact that the rural floor only affects certain states, it is a nationwide policy and applying budget neutrality on a nationwide basis minimizes the policies' impact on payments and results in all hospitals in the nation funding a nationwide policy. The redistributive effect of applying budget neutrality adjustment on a state-by-state basis could cause unnecessary hardship and create severe operational difficulties of the hospitals in the states subject to state-level budget neutrality adjustments, and could potentially put these hospitals in financial jeopardy. This policy would hamper the ability of affected hospitals to continue to provide high-quality care to Medicare beneficiaries and threaten entire communities that depend on their local hospital.

- CMS appears to be developing broad policy which attempts to target only a few RF states at the expense of other RF states which is not a way to establish good public policy

  The proposed rule points out several examples of areas which this policy would target. This would apparently be to reverse what CMS perceives to be misapplications of the

existing policies. If the existing policies are not working properly then CMS must look at the causes of why those policies are not working. If the CMS were to examine the sources of these policy issues then appropriate changes could be developed. This would avoid a non-targeted wholesale change as is proposed which sets a bad precedent for other changes that will occur in the future.

The effects of within-state budget neutrality to the hospitals in the state of New Hampshire are substantial; NHHA estimates that New Hampshire hospitals will effectively experience a cut of over $5 million annually if this provision were to be implemented

NHHA strongly opposes CMS' proposal to apply budget on a statewide basis. We believe CMS should very carefully consider the intent of Congress and the amount of financial difficulty created to the seven states that will experience large decreases in payment if it implements this proposal.

- The proposal is in stark contrast to many other "pooling" type prospective payment system (and other payment systems) funding mechanisms such as the outlier pool.

  One CMS rationale for its proposed approach is that the hospitals within the same state should pay for the application of the RF within that same state and that the additional payments made to the RF recipient hospitals in that state should not be paid by others nationally as doing so represents redistribution of payments across states. In making this statement, the CMS apparently did not examine the distribution effects of the "outlier pool" which is very disproportionately distributed. This same "outlier pool" concept applies to a wide variety of other policy areas.

  Under the "outlier pool" concept presently applied to the RF, the pool is created by an offset to the PPS rates and thereby paid by all hospitals including those that receive the RF. If one examines the distribution of the outlier payment one finds that there is a very wide redistribution of those payments. Similarly many, if not most, of the RF recipient states do not receive anywhere near the amounts they provide in contributions to the "rural floor pool" funding.

  There are many other policy adjustments that are financed from the universe of payments rather from the recipients and they are not unique to the Medicare program. The Medicaid program is financed by the federal government to states by differing matching rates to recognize the fact that there are differing levels of ability of the states to finance the coverage needed in that state.

Consistent with other pooling financing arrangements, CMS should retain the current pool financing for the RF.

- Applying the SS RF BN adjustment in the manner proposed perverts the system for the withdrawal of reclassifications and renders it impossible for hospitals to properly evaluate and withdraw geographic reclassifications. For many that do it may result in an

inadvertent decrease rather than an increase in their Medicare payments because it would decrease the RF in the state.

The proposal does not disclose or explain how the SS RF BN adjustment is calculated. Therefore, hospitals will be deluded into withdrawing their reclassifications in order to avail themselves of the Section 505 out commuting add-on as they have done in prior years. However, because of how the CMS has chosen to calculate the SS RF BN adjustment factor, withdrawing such appeals can result in a decrease in the SS RF BN adjustment factor and a resultant decrease in the hospitals' Medicare payments.

CMS has chosen to use the post reclassified AWIs for the calculation of the SS RF BN adjustment factors. Therefore, if the hospital withdraws their geographic reclassification and CMS recalculates the SS RF BN adjustment, the adjustment factor will actually decrease because CMS will use the pre-reclassified AWI for that calculation and will associate more dollars to the cost of implementing the RF. This was not disclosed to the hospitals. This information would have allowed the hospitals to make a rational determination as to what to do. In addition, it is not fair to cause hospitals to sacrifice the Section 505 add-on to avoid harm to themselves or their state that is caused by the decrease associated with the recalculation of the SS RF BN adjustment factor.

The effect of the reclassification withdrawals on the SS RF BN adjustment factor was unknown to the hospitals at the time they needed to make the reclassification withdrawal determination. Therefore, a hospital could make a determination to withdraw its reclassification, which would be consistent with prior year's practices, but that act could become detrimental to the hospital and to the state. This is solely caused by the unexplained measurement and application method utilized by CMS in measuring and applying the SS RF BN impact (a method which was never disclosed in the rulemaking). As a result of CMS' method, the RF by itself will not decrease yet the SS RF BN adjustment factor will decrease thereby reducing the RF applied to the hospitals and the state.

For this reason alone, the CMS should withdraw its proposal, as the only fair and reasonable rules are those which: the providers are aware of, understand, and are able to respond to. Rules, generally, must be fair and within the scope of the provider's response.

However, if CMS were to ultimately implement the proposed method, CMS should assure that any hospital that does not withdraw its reclassification in order to avoid the reduction in the state RF receives the Section 505 add-on adjustment to which it was otherwise entitled.

- The proposal is inconsistent with the RF concept and disadvantages higher paying rural hospitals and those hospitals would not be able to respond.

  The AWIs are developed by comparing the area average hourly wage to the national average wage in order to develop the rural AWI. In a rural area, this means that compared to an objective wage (the national average wage), the rural hospitals are paying relatively

high wages. Under the RF concept, in order to equalize the market in the state, the urban hospitals are to be increased; which is what the RF statute requires. However, CMS' proposal would require the rural hospitals in that state to receive reduced payments to derive the sum of the funds that would be paid to the state's urban hospitals.

The problem with this thinking is that compared to the objective measure (the national average wage) the rural hospitals are paying a relatively high wage and cannot reduce those wages. This creates a competitive morass for the rural higher paying hospitals as they cannot reduce their wages in response the CMS' proposed reduction in payments through the application of this policy. Because of the inability to respond to the decrease in payments, the rural hospitals will be harmed which was never the intent of the RF statute.

In the proposed rule, the CMS discusses the stated rationale for the RF. The rule states "The intent behind the rural floor seems to have been to address anomalous occurrences where certain urban areas in a State have unusually depressed wages when compared to the State's rural areas." If this is the correct rationale for the RF provision, nowhere in that rationale would it suggest that the rural hospitals with the high wages should be reduced to the level of the urban areas that were below the wages of the rural area. Actually, it has been Congress' desire to protect rather than punish rural hospitals as this proposal would. Therefore, the rationale for this proposal is internally inconsistent in that the rules explanation contorts the reasoning for the RF, rationalizing that in order to equalize the urban hospitals in the state with the rural hospitals that the rural hospitals should be reduced to subsidize those urban hospitals. CMS' response to these higher paying rural hospitals is not to pay the urban hospitals more but rather to pay all of the hospital less.

For the above reasons the proposal should be withdrawn.

- CMS has not sufficiently explained how this adjustment is performed so that it can be verified nor has CMS presented any comparison between the FFY 2009 rule changes with the changes made in FFY 2008 rule.

  In the proposed and final rule each year, the CMS discusses the method that it uses to perform certain calculations. With regard to the AWI BN adjustment which up until FFY 2007 incorporated the RF, there was a description, although very brief, of the method used to perform the calculation of the adjustment which was applied to the standardized payment rates.

  For the FFY 2008 rule, the method was changed. In that rule, there was also a brief description of the method used for the calculation that was applied to the AWIs rather than to the standardized payment rate.

  For FFY 2009, the method is again being changed to a method that would apply the RF BN adjustment on a SS basis. Under the proposal, there are different adjustment factors developed for each State. Presumably after these factors are applied and the adjustments determined the resultant adjusted AWIs are also used subsequently in other BN

adjustment methodologies. However, the rule contains no description or discussion as the how this method is carried out. In addition, there is no comparison of the aggregate RF adjustment effects incorporated in this rule change or any comparison with the amount of the add-back to the FFY 2008 rate for the FFY 2007 year under the former policy change.

In addition, there is no discussion or description that compares and/or contrasts the FFY 2008 AWI based method with the FFY 2009 SS method. It would certainly be appropriate for such a comparison given the nature of this major policy switch.

CMS must include a complete description of what they are changing and how that change compares to the prior method. This is particularly the case given the prior method has only been in place for one year and is now being proposed to be changed.

- It is not clear that the existing RF BN policy, achieved through the AWI, is not duplicative

In recent years, questions have been raised about the degree to which the RF BN adjustment has been duplicating within the specific RF and overall BN adjustment calculation. This was caused by the methodology and data. The sequencing of the adjustments could also have been a factor in the duplication. The proposed rule does not discuss the process that is used to assure that there is no duplication occurring as this change is being implemented. Now, with the proposed change, a complex set of overlay calculations is required and there is great potential that there could be an inadvertent duplication of the various adjustments if caution is not exercised.

There are other specific questions that follow from this issue as the CMS has made changes to the RF BN methodology over the last several years and questions remain about those prior calculations and the subsequent changes in methodology.

Specifically, prior to FFY 2007, the RF BN method caused a duplicating effect in the RF BN adjustment which was included in the standardized amounts and such duplications have not been corrected. **Therefore, a question arises as to why CMS is proposing a rule for FFY 2009 in which the SS RF BN calculation will duplicate those prior RF BN adjustments (which were not removed from or restored to the standardized amounts when CMS changed the RF BN methodology for FFY 2008)?**

III. Tactical and Administrative Problems with the SS RF BN Proposal and Reclassification Criteria

- Hospitals reclassifying into an area which is subject to the SS RF BN adjustment could have a higher AWI than the hospitals in that area resulting in the reclassified hospitals having an AWI higher than the domiciled hospitals creating within labor market problems.

Under present CMS policy, a hospital that reclassifies into an area can have an increasing effect on the area. If this occurs, the CMS then includes the data for the reclassifying hospital and allows that data to have an increasing effect. This would raise both the reclassified AWI and the AWI for the hospitals in the recipient area.

If the proposed SS RF BN adjustment was applied and the SS RF BN adjustment only applies to the recipient state's hospitals, there could be labor market issues under the proposed policy. If there were no SS RF BN adjustment in the home state of the reclassifying hospital, then the reclassifying hospital would have an AWI that could be much higher than the hospitals in the area into which the reclassification was made. This would create a perverse situation that would disturb the labor market which is something that the CMS has been attempting to prevent. Conversely, the reclassifying hospital could increase the AWI of the hospital in the area into which they are reclassifying which complicates the labor market.

- Increasing the reclassification threshold will reduce the effectiveness of the reclassification process, which is the domain of Congress.

  The geographic reclassification process was created by Congress to address the issues related to the labor market definitions and labor competition. CMS established and then modified the present reclassification threshold in order to restrict the number of reclassifications. Now, CMS again seeks to restrict the number of reclassifications by again increasing the threshold. To accomplish this CMS revisits its questionable approach which was deployed initially. The increase in the threshold which CMS proposes would clearly have a future effect on the number and location of the reclassifications and it will also have an effect on the RF in many states. CMS has not devoted any discussion in the rule toward this effect as it would be an important part of assessing the application of such a public policy change both the CMS and the hospitals affected.

- There is no statistical analysis in support of the change in criteria. In fact, if there were statistical support it would suggest that there is a rationale for simultaneously reducing the 108% threshold if the 84% test is increased if a normal distribution is assumed which appears to be CMS' assumption.

  In 1993, CMS initially proposed the so called 84% and 108% tests for reclassification (82%/106% for rural hospitals). These thresholds were established using a basis that was at best curious and at worse incorrect. Now, the CMS is proposing to "update" these criteria, presumably with new data. A curious note is that each and every time the reclassification criteria are "updated" fewer hospitals can qualify for reclassification.

  The reason we say curious is that based on the information CMS has presented, CMS is making the assumption that the distribution of average hourly wages is normal. However based on the information presented in the proposed rule (the 88.0%, 98.0% and 108%) indicates that a normal population should not be expected or assumed. For example, with CMS' initial and FFY 2009 analyses it derived averages of 96.0% and 98.0%; however, we would expect that these averages would be 1.0. Given this abnormal distribution, the wage reclassification criteria cannot and should not be adjusted as proposed by CMS. This was the same issue implicit in CMS' original criteria based on a similar analysis.

CMS has presented no information, evidence, or statistical analyses that suggest that it performed any statistical tests to assess the normality of the population. Absent such tests and given CMS' results there can be no assumption of normality. Therefore, CMS cannot and should not use the criteria of 88.0% and 108% as proposed.

Based on the lack of any statistical analyses presented, CMS should not adopt the proposed reclassification criteria and instead should retain the present criteria.

- Coupled with the proposed SS RF BN adjustment, increasing the reclassification threshold renders punitive damage on many areas and states, some disproportionately.

  The change in the reclassification rules being proposed cannot be properly considered without also considering the effects of this change in combination with the change being proposed for the SS RF BN adjustment. These two changes taken together will have disastrous results when both are considered simultaneously.

  This situation is influenced by the number of hospitals benefiting from that states' RF, the effects of geographic reclassification in that state's RF and the proportions of payments within the state. None of these effects are analyzed or discussed in the proposed rule. Without such analysis or discussion, CMS cannot sufficiently understand what its proposal accomplishes or what the proposals unintended downstream side effects might be. This creates the situation where the RF will decrease because fewer hospitals can reclassify out of an area and then simultaneously prevent hospitals from seeking a better AWI.

NHHA has identified and analyzed many of these effects and have found them to be undesirable. Yet, these issues are not even raised in the proposed rule which raises a question about how thorough this proposal has been analyzed. We believe it is wholly inappropriate for the agency to make budget neutral adjustments for policies that are set on the national level, such as the rural floor and budget neutral within states. **Therefore, NHHA urges CMS to withdraw the proposal, analyze these effects, and provide an in-depth discussion thereon should it chose to republish any such changes in the future. We further suggest that CMS, in collaboration with policymakers and hospital stakeholders, continue to examine other more fundamental changes to the AWI methodology that make the system more objective and rational.**

Other Proposals

- NHHA is opposed to phasing out the indirect medical education adjustment to capital payments, which cuts payments to teaching hospitals in New Hampshire by over $5.5 million over five years. Capital cuts of this magnitude will disrupt hospitals' ability to meet their existing long-term financing obligations for capital improvements. Hospitals have committed to these improvements under the expectation that the capital PPS would remain a stable source of income. Reducing capital payments will create significant financial difficulties and amounts to Medicare reneging on the full cost of caring for America's seniors and disabled. CMS has no analysis of the impact of these proposed

changes on the high-caliber medical education of our future physicians and the community-wide services on which hospitals often lose money providing, such as burn and neonatal units. It is irresponsible of CMS to make such changes without a clear understanding of the broader ramifications. **NHHA reiterates its opposition to these unnecessary cuts, which ignore how vital these capital payments are to investments in the latest medical technology, ongoing maintenance and improvement of hospitals' facilities and medical education.**

- **NHHA is opposed to expanding the post-acute care transfer policy to include patients receiving home health care services within seven days of discharge, which is estimated to reduce payments to New Hampshire hospitals by over $1 million over five years.** The expansion of the post-acute transfer policy inappropriately penalizes hospitals for efficient treatment and ensuring that patients receive the right care at the right time in the right place.

Hospital Quality Data

- **NHHA opposes CMS including any quality measures in the 2010 payment determination that have not been endorsed and/or adopted by both the National Quality Forum (NQF) and Hospital Quality Alliance (HQA).** Adding such a large number of disparate measures is an unfocused approach to quality reporting that provides no direction to hospitals on quality improvement priorities. Of the proposed measures, only 10 have been adopted by the Hospital Quality Alliance (HQA). We do not believe that the other 33 measures proposed by CMS are ready for reporting at this time.
- **NHHA opposes CMS's proposed expansion of the list of "hospital-acquired conditions" by nine additional conditions when the payment policy takes effect on October 1 and believes only four of the total 17 conditions are ready to include for FY 2009.** The remaining conditions should not be implemented for FY 2009 because they are not reasonably preventable, it is difficult to determine whether they are present on admission, or the patient population included by CMS is too broad.

If you have any question regarding these comments please contact myself or Paula Minnehan, VP, Finance and Rural Hospitals at pminnehan@nhha.org or 603-225-0900.

Sincerely;

Mike Hill

Michael Hill, President