VIA http://www.regulations.gov

Marilyn Tavenner
Acting Administrator, Chief Operating Officer
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1588-P

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals’ Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers; 77 Fed. Reg. 92, 27,870 et seq. (May 11, 2012); CMS-1588-P

Dear Ms. Tavenner:

Trinity Health is one of the largest Catholic health care systems in the country. Trinity Health is comprised of 49 acute-care hospitals, 432 outpatient facilities, 32 long-term care facilities, and numerous home health offices and hospice programs in ten states – California, Idaho, Indiana, Illinois, Iowa, Maryland, Michigan, Ohio, Oregon, and Nebraska. Our hospitals and clinics employ nearly 1,500 physicians, and we work with another 9,500 physicians through our open medical staff model.

On behalf of Trinity Health, we are pleased to submit comments on the notice of proposed rule making for the Fiscal Year 2013 Hospital Inpatient Prospective Payment System. Specifically, we are providing comments on the following proposed changes:

- MS-DRG Documentation and Coding Adjustment
- Hospital Readmission Reduction Program
- Hospital Inpatient Quality Reporting Program
- Value Based Purchasing Program
- Changes to the clarification of regulations regarding the duration of classification for Sole Community Hospitals
- Changes in New Program Growth from 3 Years to 5 Years for Calculating Direct GME Caps for New Teaching Hospitals

1. Proposed MS-DRG Documentation and Coding Adjustment

a) General Acute Care Hospitals

In the FY 2012 rule making cycle, pursuant to their authority under section 7(b)(1)(B) of Public Law 110-90, CMS implemented a -2.0 percent prospective adjustment to the standardized amount to partially eliminate the full effect of the documentation and coding changes in FY 2008 and FY 2009 claims that do not reflect real changes in case-mix on future payments. For FY 2013, CMS proposes a final prospective reduction of 1.9 percent to the standardized amount to
complete adjustments for increases in the case mix index for FY 2008 and FY 2009 arising from the transition to MS-DRGs. Additionally, CMS is also proposing a prospective 0.8 percent reduction to adjust for increases in the FY 2010 case mix index as a result of documentation and coding improvements. These cuts will have a significant impact on Trinity Health, reducing reimbursement to our hospitals by $13 million in FY 2013.

We respectfully submit that CMS’s methodology fails to account for historical trends in case mix growth and is thus a flawed methodology. Trinity Health supports the American Hospital Association’s (AHA) analysis which found that there is a fundamental flaw in CMS’s methodology for determining the effect of documentation and coding. Accordingly, we respectfully request that CMS withdraw the proposed 1.9 and 0.8 percent cuts as these cuts are based on a flawed analysis and are thus not valid figures. Before proceeding further with documentation and coding adjustments, we strongly urge CMS to revisit its analysis and caution CMS regarding the serious consequences of implementing such significant cuts at a time when hospitals will be making major investments to help reform the health care delivery system through clinical integration.

b) Proposed MS-DRG Documentation and Coding Adjustment for Hospitals Reimbursed Based on the Hospital-Specific Rate

The Sole Community Hospital (SCH) program helps to ensure continued access to needed health services for program beneficiaries in rural communities. The SCH program ensures the viability of hospitals that are geographically isolated and thus play a critical role in providing access to care. Hospitals qualify for SCH status by demonstrating that because of distance or geographic boundaries between hospitals they are the sole source of hospital services available in a wide geographic area. There are a variety of ways in which hospitals can qualify for SCH status, but the majority qualify by being more than 35 miles from another provider. Currently, approximately 450 hospitals in 46 states have SCH status.

SCHs are paid based on the Federal rate or their hospital-specific payment rate (HSP) from 1982, 1987, 1996 or 2006, adjusted for inflation, whichever yields the highest aggregate payments for the year.

In the FY 2011 IPPS rulemaking cycle, CMS proposed and finalized a policy to apply a permanent -2.9 percent documentation and coding adjustment to the HSP pursuant to broad authority granted the Secretary under section 1886(d)(5)(I)(i). Under this same authority, in FY 2012, CMS finalized a prospective adjustment to the HSP of -2.0 percent. In FY 2013, CMS is proposing to complete the remaining prospective adjustment to account for the documentation and coding effects that occurred in FY 2008 and FY 2009 by applying a -0.5 percent adjustment to the HSP. For FY 2013, CMS is also proposing a prospective 0.8 percent reduction to adjust for increases in the FY 2010 case mix index as a result of documentation and coding improvements.

Trinity Health urges CMS to remove the 4.9 percent documentation and coding adjustment applied to SCHs for FY 2012 and to rescind the 0.5 and 0.8 percent documentation and coding adjustment proposed for FY 2013 for SCHs and Medicare Dependent Hospitals (MDHs). Trinity Health and numerous other hospitals with SCH or MDH
status have sought judicial review of CMS’s authority to apply the documentation and coding adjustments to the HSP. Therefore, at a minimum, we request that CMS delay finalizing the proposed 0.5 and 0.8 percent reduction for FY 2013 until the issue is decided by the courts. Our rationale is delineated below.

First, CMS lacks statutory authority to apply the documentation and coding adjustment to the HSP Rate. Trinity Health respectfully submits that CMS does not have the authority to apply the documentation and coding adjustment to the HSP. As CMS has acknowledged, section 1886(d)(3)(A)(vi) only authorizes application of a documentation and coding adjustment to the standardized amount. The section does not authorize application of such an adjustment to the HSP. In light of Congress’s specific and unambiguous directive regarding the narrow applicability of this type of adjustment, it is inappropriate – and impermissible – for CMS to apply the adjustment to the HSP.

Second, applying the documentation and coding adjustment threatens the SCH program, as well as the ability of these hospitals to provide care in isolated communities. Congress established the SCH designation and its attendant benefits to identify and buttress hospitals that, by reason of their geographic isolation, are critical to the healthcare infrastructure of their communities and are financially vulnerable. Congress has long appreciated the special role of SCHs and the need to afford these hospitals special recognition and protections under the Medicare program to ensure their continued viability. As such, policies that CMS adopts that affect SCHs should be consistent with the intent of the SCH program, and seek to avoid any unnecessary insult. Applying the documentation and coding adjustment to SCHs will adversely impact these hospitals. The permanent downward adjustment of 2.9 percent in FY 2011, 2.0 percent in FY 2012, and the proposed permanent downward adjustments of 0.5 and 0.8 percent in FY 2013 jeopardize the safety net these hospitals provide.

2. Hospital Readmission Reduction Program (HRRP)

For FY 2013, CMS proposes a final framework the Hospital Readmission Reduction Program required under the Affordable Care Act. Trinity Health has the following comments with regard to the HRRP methodology proposed thus far.

a. Exclusions from Readmissions Measures

CMS proposes to exclude from the AMI 30-day risk standardized readmission measure some planned readmissions for percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG). CMS does not propose to exclude any readmission from either the HF 30-day risk standardized readmission measure or the PN 30-day risk standardized readmission measure. While hospitals may be able to prevent some portion of readmissions, some readmissions are planned as part of a patient’s treatment plan or are unrelated to the initial admission. To penalize hospitals for such admissions seems to be unfair and illogical. Trinity Health urges CMS to exclude all planned readmissions and readmissions unrelated to the initial admission from the readmissions measure.
b. **Maryland Hospitals**

Trinity Health supports exemption of Maryland hospitals from the Hospital Readmissions Reduction Program. Trinity Health urges CMS to continue to support the innovative all-payer system in Maryland, as recommended by the Maryland Hospital Association in its comments stated in June 21 letter, particularly with respect to continuing Maryland’s exception from the HRR program given its very successful, ongoing program, and exempting the State and all its hospitals from the VBP program for the same reason. The State remains committed to meeting or exceeding Federal performance standards.

c. **Implementation of the Proposed Readmission Adjustment Factor**

In the FY 2013 Proposed Rule, CMS explicitly defines both the source of data and ratio calculation methods. The agency also indicates, by publishing a list of proposed readmission adjustment factors, how individual providers are likely to fare under the HRRP. It is not clear, however, how the HRRP will be implemented (i.e. through individual claims adjustments, cost report adjustments, etc.) This is in contrast to the Proposed Rule’s discussion of implementation of the Value Based Purchasing Program. With regard to that Program, CMS is clear that it intends to apply any adjustment under the program on a claims basis. **As such, Trinity Health requests that in the FY 2013 Final Rule, CMS provides and allows comment on its proposed methodology for implementing the hospital readmission adjustment factor.**

3. **Hospital Inpatient Quality Reporting (IQR) Program**

Trinity Health supports Medicare’s efforts to promote increased quality and efficiency of care. Specifically, Trinity Health supports the Hospital IQR and Hospital Value-Based Purchasing Programs. For FY 2015, CMS proposes to add hospital-wide readmission rate (NQF #1789) as an IQR measure.

Measure #1789 was approved by the National Qualify Forum (NQF) on April 24, 2012. Approval of this measure, however, is being formally appealed by member organizations because fewer than 20 percent of the more than 400 NQF members voted on the measure. It is also being appealed because less than 50 percent of those voting on the measure were in favor of approval. Stakeholder concerns with the measure focus on the list of planned admissions allowed as well as the absence of an adjustment that accounts for socioeconomic status. Trinity Health shares other provider concerns and believes that the list of planned admissions for the measure should be considered further and that socioeconomic status should be factored into calculation of the rate. **Trinity Health urges CMS to withdraw its proposal to include the hospital-wide readmission rate measure for FY 2015 until the NQF appeal is settled.**
4. **Hospital Value Based Purchasing (VBP) Program**

The statute requires CMS to implement the Medicare Value-Based Purchasing program in a manner that is budget neutral. To fulfill this requirement, CMS proposes to adjust on an ongoing basis Medicare inpatient claims. Insofar as CMS will not have systems in place to implement this policy at the start of the federal fiscal year, CMS is proposing to implement this policy beginning January 1, 2013 and to reprocess claims with dates of service between October 1, 2012 and December 31, 2012 that are submitted before January 1, 2013. Trinity Health is opposed to the CMS proposal to reprocess claims due to the administrative burden that will be placed on hospitals. We recommend that the program not be implemented until CMS systems are in place. Alternatively, if budget neutrality is an issue, we recommend that the program not be implemented until CMS systems are in place and that the VBP adjustment factors be revised to achieve budget neutrality over the remaining fiscal year 2013.

Trinity Health understands that DSH, IME, and other adjustments are not impacted under the VBP program. However, in the proposed rule, it is not entirely clear how CMS intends to adjust payments under the VBP program to ensure that these adjustments are not impacted. As such, Trinity Health requests that CMS articulate and allow comment on how it will direct Medicare contractors to operationalize the VBP adjustment factor so that DSH, IME and other excluded payments are not inadvertently impacted.

5. **Clarification of Regulations Regarding the Duration of Classification for Sole Community Hospitals**

According to CMS, existing Medicare regulations require an SCH to notify its fiscal intermediary or MAC if certain changes affecting its eligibility occur, but do not explicitly address the situation where a hospital never met the requirements to become an SCH. As such, for FY 2013, CMS proposes to revise the regulations to clarify its current authority that if CMS determines that the hospital was incorrectly classified as an SCH, SCH status could be revoked retroactively consistent with other Medicare regulations.

Trinity Health believes that this change is unfair to hospitals and unnecessary. If CMS approved a hospital's request for SCH status, unless there were fraudulent misrepresentations made by the hospital in its request for SCH status, the hospital had no way of knowing that it did not qualify in the first instance. In the example provided by CMS, the hospital would have clearly believed that it qualified for SCH status, as did the fiscal intermediary reviewing the hospital's request, and CMS, which ultimately approved the hospital's application. If CMS on some basis later determines that the hospital did not meet the qualification terms, CMS should then revoke the hospital's status prospectively. To do so retroactively punishes the hospital for a mistake made by CMS of which the hospital had no knowledge. If the hospital had knowledge that it did not meet the qualification terms, then the hospital knowingly made a false statement, and fraud existed in the application. Short of that, CMS's proposal punishes the hospital for a mistake made by the agency. Of course, if fraud existed in the original request, then CMS has ample authorities in existing regulations to revoke the SCH status back to the original conferral, as well as to take other actions. Hospitals with SCH status act in reliance on that status. They establish programs, hire personnel, and generally budget based on an expected revenue. For CMS to...
revoke a hospital’s SCH status and seek to recoup payments made based on that status retroactively, when the hospital had no knowledge of CMS’s mistake, is patently unfair and potentially destabilizing to a hospital that is already in a vulnerable position (or it would not have SCH status). For these reasons, Trinity Health urges CMS to revoke this proposal, and instead use its already existing authorities to revoke a hospital’s SCH status prospectively if the agency determines that the hospital does not qualify, except in instances of fraud, where the agency can utilize other existing authorities to make retroactive recoupments.

6. Proposed Changes in New Program Growth from 3 Years to 5 Years for Calculating Direct GME Caps for New Teaching Hospitals

As the result of a variety of internal and external pressures, multiple hospitals throughout Trinity Health have recently considered and/or established new residency training programs to address specific imperatives, such as projected shortages in the physician workforce. It is Trinity Health’s experience that GME initiatives are highly complex and multifaceted. Hospitals desirous of participating in GME must collaborate closely with numerous internal and external stakeholders, including administrative and medical staff leadership, one or more accrediting bodies (e.g., ACGME, AOA), regulatory agencies such as CMS, academic affiliates, and others.

The ability of a hospital to qualify for GME reimbursement through Medicare is an important consideration in determining the feasibility of establishing and sustaining GME training programs. The current new teaching hospital exception, which allows for a hospital to establish a resident FTE cap during a narrow 3-year window, is predicated upon an unreasonable and aggressive expectation that an organization can establish its desired complement of training programs nearly simultaneously in such a period while ensuring a high-quality educational experience for residents and fellows and a seamless transition from a nonteaching to a teaching service care model for Medicare beneficiaries.

As CMS acknowledges in its proposed rule, it is not appropriate to limit hospitals’ access to GME reimbursement on the basis of factors that are beyond the hospitals’ control, principally: requirements and standards dictated by agencies external to the hospital, such as the duration of the ACGME review cycle for new program accreditation, the calendar of events promulgated by the National Resident Matching Program (NRMP), and the roughly fixed annual May/June graduate date for medical students. Accordingly, CMS has proposed that the resident FTE cap establishment window be extended from 3 to 5 years.

Trinity Health wishes to express its full support for this proposed change. Furthermore, Trinity Health believes that CMS’ proposed expansion of the cap establishment window is regrettably overdue, in light of significant activity that has taken place during the past decade to expand residency training to address national and regional physician shortages and complement the development of new medical schools. Many hospitals, including two Trinity Health member hospitals, have recently or are currently in the process of establishing new programs and will be negatively impacted by inherent limitations associated with establishing a resident FTE cap under the existing regulations.
Trinity Health therefore recommends that CMS consider making the proposed rule effective for hospitals that begin training residents in new programs for the first time on or after October 1, 2012, as is stated in the proposed rule, as well as for those new teaching hospitals that have already begun training residents, but which are within the current 3-year cap establishment window as of October 1, 2012 (i.e., those hospitals that have yet to establish a permanent resident FTE cap but are in the process of qualifying to do so under the new teaching hospital exception).

It is Trinity Health’s position that the financial impact beyond the extension from 3 to 5 years of our recommended refinement to the proposed rule (i.e., the application of the new rule to hospitals that are currently within the 3-year cap establishment window) will be negligible from CMS’ perspective but could be significant to those hospitals that would be affected. We believe that extending the effect of the proposed changes to these hospitals is very much in keeping with CMS’ stated purpose of aligning the cap establishment window with the period of time in which it is reasonable for new teaching hospitals to develop GME programs.

7. Proposal for Counting Labor and Delivery Beds in the Formula for Determining the Payment Adjustment for Disproportionate Share Hospitals and IME Payments

We recognize that CMS’ proposed treatment of ancillary labor and delivery beds for purposes of the IME payment formula, specifically the resident-to-bed ratio calculation, is the most recent in a series of proposed changes aimed at achieving common methodological treatment in how CMS counts patient days and available bed days for DSH and IME payment calculation. While the goal of achieving common treatment of patient and bed days may appear rational as it relates to the fee-for-service payment system, the design of the proposed rule does not evidence sufficient consideration of the Medicare GME payment system nor the potential immediate negative and disproportionate impact that would result from implementation of this rule.

Given the size and diversity of Trinity Health and its GME enterprise, we have experience with selected hospitals within our system that have historically been unintentionally disadvantaged under the payment formulas based on the hospitals’ characteristics. Therefore, our concerns with this specific section of the rule as it is proposed are that it would:

- Methodologically codify the inclusion of a subset of a hospital’s beds that are generally not available to Medicare beneficiaries.
- Disproportionately and negatively impact those hospitals that offer women’s and children’s services.
- Exacerbate IME payment differences among hospitals in a manner unrelated to services provided to Medicare beneficiaries.

In 2010, CMS changed the way that patient days associated with ancillary labor and delivery beds are counted in the DSH payment calculation. The result of this change was positive but marginal, as CMS appropriately began counting some incremental number of additional patient days that warrant inclusion in the DSH calculation, as such days are associated with services provided under IPPS. To achieve common methodological treatment of patient days and available bed days, CMS is proposing to include ancillary labor and delivery available bed days in the IME payment calculation, as well.
However, a review of the demographics of the Medicare population highlights how unreasonable it is to consider these beds as routinely available to the hospital's population of Medicare patients. In excess of 90% of Medicare beneficiaries are either over 65 years of age and/or male and are therefore not eligible to occupy ancillary labor and delivery beds during an inpatient stay. In contrast to the change to patient days made in 2010, the proposed change to add available labor and delivery ancillary bed patient days to the denominator of the resident-to-bed ratio calculation will have an immediate, significant, and negative impact on the resident-to-bed ratio and, in turn, the IME payments calculated from the formula.

We conclude that despite the intent of the proposed rule change (i.e., common treatment of patient days and available bed days), implementing this proposed change will reflect an ill-conceived piecemeal reduction to IME funding that was developed in the context of the fee-for-service Medicare payment system and ignores the imperatives of the Medicare GME payment system. Those institutions that are already most disadvantaged by the current GME payment formula, (i.e., institutions that serve proportionally higher non-Medicare populations, such as women and children's hospitals), will be most severely impacted by the proposed change. Implementing the change will further and unnecessarily exacerbate inequities in the GME funding formula and could be devastating to GME programs at affected institutions that provide much of the undergraduate medical education and GME training in primary care, including family medicine, obstetrics and gynecology, and pediatrics.

We urge CMS to reconsider the immediate implementation of this proposed change in light of its significant and disproportionate negative impact. Further, we request that CMS consider a detailed analysis of the potential impact of this change as part of a comprehensive study of the GME payment formula.

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Trinity Health appreciates the opportunity to submit comments for your consideration. If you have any questions about these comments, please contact Tonya Wells at (248) 489-6068.

Sincerely,

Paul Sahney
Chief Revenue Office and Vice President of Finance

Tonya K. Wells
Vice President of Federal Public Policy and Advocacy

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