THE
CATHOLIC HEALTH
ASSOCIATION
OF THE UNITED STATES

September 2, 2008

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1404-P

RE: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates; Proposed Rule

Dear Mr. Weems:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the above notice of proposed rulemaking (NPRM), published in the *Federal Register* (Vol. 73, No. 139) on July 18, 2008.

WASHINGTON OFFICE
1875 Eye Street, NW
Suite 1000
Washington, DC 20006-5409
Phone 202-296-3993
Fax 202-296-3997
www.chausa.org

1. Volatility of APC Relative Weights

CHA continues to object to the year-to-year volatility of the ambulatory payment classification (APC) weights and urges the Centers for Medicare and Medicare Services (CMS) to take appropriate steps to ensure stability in APC weights.

As has been the case in other years, the CY 2009 proposed rule shows significant swings in the APC relative weights. For 24 APCs, the proposed CY 2009 weights would decrease by 10 percent or more; for 10 of these, the reduction is greater than 20 percent and for 4 it is greater than 35 percent. In total, weights would be lower for 107 APCs. On the other hand, weights increase for 311 APCs, going up at least 10 percent for 55 of them. In fact, 30 APCs rise by at least 20 percent and 15 APCs gain 35 percent or more. For 25 APCs, no comparison could be made. Note that these comparisons are confounded by the fact that they do not include drugs and biologicals.

We continue to recommend as one approach to adjust medians derived from claims data to limit the amount of change that occurs from year-to-year. From the perspective of both hospital operations and payment policy, a stable payment environment is desirable. A stability policy should adjust the medians from claims data to ensure that no APC's median falls more than 5 percent compared to the medians used for payment in 2007.

2. Proposed Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged

Payment for Specified Covered Outpatient Drugs (SCODs) other than Radiopharmaceuticals. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that payment for specified covered outpatient drugs for CY 2006 and succeeding years be equal to the average acquisition cost for the drug for that year as determined by the Secretary based on the hospital acquisition cost survey data collected by the GAO in 2004 and 2005 and subsequent CMS surveys, and subject to any adjustment for overhead costs. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary.

To set the proposed rule rates for CY 2009, CMS evaluated two data sources: fourth quarter 2007 average sales price (ASP) data and mean costs derived from CY 2007 OPPS claims data. As in past OPPS rulemaking, CMS cites a 2005 MedPAC survey of hospital charging practices which indicated that hospitals set charges for drugs, biologicals, and radiopharmaceuticals high enough to reflect their pharmacy handling costs as well as their acquisition costs. Thus, CMS asserts that the mean costs calculated using charges from hospital claims data converted to costs are representative of hospital acquisition costs for these products, as well as their related pharmacy overhead costs. CMS concluded that using mean unit cost to set the payment rates for the drugs and biologicals would be equivalent to basing their payment rates, on average, at ASP+4 percent, and this is the recommended payment rate for CY 2009 for drug and biological acquisition and pharmacy overhead costs combined.

CHA believes that:

- **The current reimbursement rate for SCODs at ASP+5% is inadequate to cover acquisition cost, let alone pharmacy services and handling, and the proposed rate of ASP+4 is even worse.**

- **CMS has failed to appropriately pay for pharmacy services. A growing body of evidence (see below) shows that CMS's methodology for calculating payment for separately paid drugs is**

deeply flawed and contrary to the statute, yet CMS proposes no immediate corrections.

- **Instead CMS proposes changes to hospital cost reports that would impose significant burdens on hospitals and the agency and would affect payment no earlier than 2011. The data produced by these changes likely will not merit the investment of significant time and effort by hospitals and CMS to implement these changes.**

- **Neither the Government Accountability Office nor CMS have conducted surveys of hospital acquisition cost since 2004, as required by statute.**

- **Although CMS claims that its methodology is the "best currently available proxy for average hospital acquisition cost and associated pharmacy overhead costs," several analyses[1] show that CMS's methodology produces rates that do not represent hospital acquisition cost and pharmacy overhead.**

    - **CMS does not conduct a survey of hospital acquisition cost as required by law.**
    - **CMS does not reimburse drugs at the rates applicable in physicians' offices, which is required by law if the hospital acquisition cost data are not available.**
    - **In fact, CMS's methodology is not a survey; it is an inaccurate extrapolation from claims data.**

- **Therefore payment should be based on ASP+6 (or the rates under the Competitive Acquisition Program).**

3. Reporting Quality Data for Annual Payment Updates

CHA has a number of comments regarding the proposed rule's sections on the reporting of outpatient quality data and the related reduction in OPPS payment for hospitals failing to meet data reporting requirements. At the outset, however, we wish to note that CHA has consistently supported high quality patient care, regardless of the setting, and maintains the goal of building a national quality reporting system that provides standardized, useful information to public and

[1] These analyses include a 2005 MedPAC report that found the CMS methodology significantly understated pharmacy costs – saying that such costs make up 26 percent to 28 percent of pharmacy departments' direct costs. Another study by RTI done in 2008 said that the CMS methodology substantially underestimates the costs of acquiring and suppling separately paid drugs. Finally, a 2006-2008 study performed by a stakeholders group found that the CMS methodology produced wildly inaccurate estimates of unit cost for individual drugs and is inaccurate in the aggregate as well.

private payors, patients and their families, regulatory and accrediting bodies, and other stakeholders in the health care delivery system.

- **Measures Proposed for 2010 Payment**

For payment of a full update factor in 2010, CMS proposes that reporting on four new imaging measures would be required, along with continued reporting on the seven quality measures in place during the initial implementation of the Hospital Outpatient Quality Data Reporting Program (HOP QRDP) in 2008.

When proposing new measures, such as the imaging efficiency measures, we believe that CMS should provide information essential for analyzing the proposal. This includes measure specifications and the rationale for proposing the measure. Moreover, we believe that a measure should have received National Quality Forum (NQF) endorsement prior to being proposed for adoption by CMS. For the imaging measures, none of these tests are met. We also believe that new measures should be thoroughly tested prior to being proposed for use, and that data regarding new measures should be collected for some reasonable period of time before being made public in order to determine whether the new measures are having their intended impact. Further, public reporting of a new measure should be deferred so as to permit hospitals to use the measure for internal quality improvement for a period of time. We believe that all of these steps would help assure the adoption of appropriate performance measures and continued progress in improving the quality of care in a non-threatening climate.

Failure to provide the information noted above makes it difficult for us to offer sufficiently informed input on the proposed new imaging measures. We would, however, note that measures relating to the use or non-use of contrast appear to be improperly targeted since it is physicians, not individual hospitals, who make the decision about whether to order an imaging study involving or not involving the use of contrast agents.

In light of the points made above, we urge CMS to drop the four proposed imaging measures, given CMS' failure to provide the public with the information needed to provide meaningful comments and until such essential issues as measure specification, NQF endorsement and pilot testing can be accomplished.

- **Process for Updating Measures**

CMS proposes to establish a sub-regulatory process that would allow the agency to update the technical specifications for measures at any time during a reporting period based on evidence and guidance from NQF or another consensus-building entity. **We strongly oppose such a subregulatory process**. Measure selection and the accompanying technical specifications should be announced once a year through rulemaking, allowing the public to comment. Mid-stream

changes in measure specifications, essentially at any time during a reporting period, would be burdensome for hospitals to monitor and implement, and would be disruptive to data collection and reporting processes.

- **Possible Measures for 2011 and Beyond**

CMS seeks comments regarding an additional 18 measures that might be used in hospital outpatient quality reporting in 2011 or later.

The list of proposed measures strikes us as unduly broad. We urge CMS to work with stakeholders, especially the NQF and the Hospital Quality Alliance (HQA), to prioritize any new measures and to expand the list of measures relatively slowly and with care. CHA believes that quality improvement is best served through focused action on key priorities. In our view, adding disparate measures across many conditions will not improve systematic delivery of care and will be extremely costly to implement.

Further, as noted earlier, when proposing new measures CMS should provide information on measure specifications for each proposed measure. In addition, CMS should provide a rationale for each measure, discuss the evidence underlying the measure, and explain the expected value of putting the measure into place. Moreover, in the hospital outpatient setting, the patient population is extremely diverse, ranging from acutely ill patients presenting to the emergency department to relatively healthy patients presenting for relatively routine screening tests, such as colonoscopy. We, therefore, believe that CMS needs to spell out the intended target population for new measures. For the 18 proposed measures, none of this was done. Without the kinds of information noted above, we believe it is difficult, if not impossible, for hospitals to provide meaningful input to CMS regarding proposed measures.

Finally, we believe that any additional OPPS measures should relate to matters under hospital control, not matters that are primarily the purview of the individual treating physician. It would appear that many of the 18 measures proposed for future use do not meet this important test

- **Data Reporting Requirements under HOP QDP for 2010 Payment**

The proposed rule includes the data reporting requirements that hospitals would have to meet in order to receive a full OPPS update factor in 2010. We have comments regarding several of these requirements.

First, for 2010, CMS proposes that all hospitals sharing the same CMS certification number (CCN) would be required to combine data across multiple campuses for all clinical data measure submissions. Data would be publicly reported on the CMS web site by CCN, but CMS would indicate where data from two or more hospitals are combined. Hospitals sharing the same CCN would also

complete a single notice of participation form. **We support this proposal since we believe it is appropriate to align clinical and financial reporting.**

Second, a data validation requirement is proposed for the 2010 update (none is included in the HOP QRDP for the 2009 update). More specifically, CMS proposes to select a random sample of 50 episodes of care from among those submitted by a hospital beginning in January 2009, with the hospital requested to submit accompanying medical record documentation for the selected cases. A CMS contractor would re-abstract the information, compare it to that submitted by the hospital and provide feedback to the hospital. Further, unlike the inpatient quality reporting program, which requires a sample of 5 cases from each hospital each quarter, the proposed validation program would require validation for only 800 randomly selected hospitals each year, about 20 percent of participating hospitals. CMS also seeks comments on three alternative validation methodologies for 2011. One alternative would be to use the inpatient validation methodology of sampling five records from each hospital each quarter. A second alternative would be to develop criteria to target validation based on concern about the accuracy of a hospital's data submission. The third alternative would combine the first two approaches. We appreciate the opportunity to provide feedback on all of these options. **The proposal to sample 50 episodes from 800 hospitals could be acceptable, depending on the specific details of implementation: for example, the process for selecting and notifying hospitals. CMS should also consider for 2010 and subsequent years the "combination" option identified as an option for 2011, or an alternative combination approach that would pair option two with the proposal to random sample 50 episodes from 800 hundred hospitals.**

Third, CMS proposes that the validation score would be based on the percent agreement for each clinical measure rather than on individual data elements (the approach used in the inpatient program). **We support the proposed "measure based" methodology because we find it more clinically meaningful than one based on individual data elements.**

Fourth, to receive a full update, CMS proposes that a hospital would need to pass a validation requirement of at least 80 percent, using an upper bound of 95 percent confidence interval. However, CMS has never adequately explained the methodology used in developing this upper bound of 95 percent confidence interval, instead simply referring readers to text books on sampling techniques and survey sampling, published in 1977 and 1964, respectively. **We ask that CMS provide more information about the methodology directly in the final rule and give an example of its application as well.**

Fifth, the proposed rule briefly discusses CMS's intentions with respect to making information collected under the HOP QDRP public by posting it on the CMS Web site. **In this regard, we would encourage CMS to post this information on the existing Hospital Compare Web site that is already being used for publicly disclosing inpatient performance data.** This would permit "one-stop shopping" for Medicare beneficiaries and other interested parties.

Finally, a mandatory reconsideration and appeals process is proposed for 2010 payment decisions. Hospitals requesting reconsideration would submit a reconsideration request via the QualityNet web site. A hospital dissatisfied with the outcome of the reconsideration could appeal to the Provider Reimbursement Review Board. This process is modeled after the process adopted for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. **Our major concern with the process has been the unduly long time it takes for hospitals to learn CMS's decision on their reconsideration request, as much as five months in our experience. We, therefore, urge CMS to take whatever steps are possible to produce more timely decisions**.

ASC Quality Data Reporting

The proposed rule once again proposes to defer implementation of a quality data reporting program for ambulatory surgical centers (ASCs) and invites public comment on the deferral. We agree that such deferral is appropriate. ASCs need more time to adapt to the new Medicare ASC payment system and to develop the infrastructure and procedures necessary for quality reporting purposes. Nevertheless, we believe that quality reporting in all settings is important to overall patient care and would be supportive of a similar program for reporting in the ASC environment. Of course, movement into the ASC environment should be preceded by thorough and complete field testing.

4. Healthcare-Associated Conditions

In the proposed rule, CMS seeks public comment on the application of the IPPS preventable hospital acquired conditions (HACs) payment policy to the OPPS, noting that the acronym HAC would now stand for healthcare-associated conditions. CMS notes that the principle behind the HAC payment provision (Medicare not paying more for healthcare associated conditions) could be applied to the Medicare payment systems for other settings of care, including hospital outpatient departments and ASCs. In any case, CMS is not proposing new Medicare policy and is simply seeking public comments on options and considerations, including statutory authority, related to extending the IPPS hospital-acquired conditions payment provision for hospitals to the OPPS.

We agree with CMS that application of the HAC concept to the OPPS setting would be extremely challenging, especially since payment in that setting is not driven by patient diagnosis and the concept of present on admission would be difficult to apply there. We also believe that explicit statutory authority would be required for this purpose given that the existing authority at section 1886(d)(4)(D) speaks only to the IPPS setting.

Second, any application of the HAC concept to the OPPS setting would be appropriate only for conditions that are reasonably preventable through evidence-based methods of prevention and under the control of the hospital. For many conditions, it is simply unreasonable to assume that prevention is possible one

hundred percent of the time even if the best guidelines are followed to the letter. Given that, it would not be appropriate for a hospital to be penalized for its failure to prevent a particular complication or condition when it has taken all appropriate steps recommended by available guidelines.

Third, the application of the HAC concept to the hospital outpatient setting would require the development of clear and specific clinical coding guidelines for any condition selected for inclusion in such an initiative.

Overall, CHA recommends that CMS acquire more experience with the HAC concept in the inpatient setting before giving further consideration to its potential application to the hospital outpatient

5. OPPS: Wage Index

CHA supports the use of the hospital inpatient area wage indexes as were tentatively finalized for FY 2009 IPPS final rule published in the *Federal Register* on August 19, 2008 for use in the CY 2009 OPPS.

6. OPPS: Outlier Payments

CHA supports the proposal to increase fixed-dollar outlier threshold for CY 2009 in order to keep the outlier payment percentage to 1 percent of the estimated total payments.

For CY 2009, CMS proposes to continue the current policy of setting aside 1.0 percent of aggregate OPPS payments for outlier payments.

For CY 2008, the outlier threshold is met when the cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and also exceeds the APC payment rate plus a $1,575 fixed-dollar threshold. For CY 2009, CMS proposes that outlier payments would be triggered when a hospital's cost of furnishing a service or procedure exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus a $1,800 fixed-dollar threshold.

7. Inpatient Only Procedures

CHA continues to urge the elimination of the inpatient list primarily because the list is not binding on physicians.

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the hospital outpatient prospective payment system (OPPS)**.** There are numerous problems created by the inpatient list as has been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Consequently, since the physician receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the

physician to be concerned whether Medicare will pay the hospital for the procedure. This is a particularly troubling issue in teaching hospitals. This fact underscores the reality that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that "[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion." While such education is important, it alone will not solve the problem. When it comes to economic issues physicians, quite understandably, pay little attention to how hospitals are paid. The CMS provider education staff does not appear to have made any headway on this matter.

Should CMS decide to retain the inpatient list, we urge the agency to consider developing an appeals process to address those circumstances in which payment for a service provided on an outpatient basis is denied because it is on the inpatient list. This would provide the hospital an opportunity to submit documentation to appeal the denial, such as physician's intent, patient's clinical condition, and the circumstances that allow this patient to be sent home safely without a more costly inpatient admission.

In closing, thank you for the opportunity to review and comment on the proposed hospital outpatient PPS rule for CY 2009.

Sincerely,

Sr. Carol Keehan, DC
President and CEO