Catholic Health Association of the United States

A Passionate Voice for Compassionate Care

September 6, 2013

Ms. Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Herbert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS-1601-P

Re: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Ms. Tavenner,

The Catholic Health Association of the United States (CHA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the above notice of proposed rulemaking (NPRM), published in the *Federal Register* (Vol. 78 No. 139) on July 19, 2013.

As a general comment, CHA is very concerned about the paucity and accuracy of information provided in the proposed rule in several areas. This lack of information seriously comprised our ability to assess the impact of the proposed policies on our members and to develop our position on the proposals. For many of the proposals, especially those dealing with collapsing visit codes, the expanded packaging and comprehensive APCs, the proposed rule did not provide sufficient information to determine and replicate how the rates were established or to evaluate the impact on our mission and providers. CHA urges CMS not to finalize these policies and to consider re-proposing them in a future year with appropriate transparency, policy details, and impact information. We wish to emphasize that we agree with the general direction of many of these are policies and that our inability to support them at this time stems from a need to know more about them before endorsing them.

1. Volatility of Ambulatory Payment Classification (APC) Relative Weights and of Year-to-Year Payments

CHA long has been concerned about year-to-year volatility of the APC relative weights and rates, and we continue to urge the Centers for Medicare & Medicaid Services (CMS) to take appropriate steps to ensure stability in APC weights and payment rates.

We appreciate the changes that CMS has made in recent years to improve stability of the rates and we recognize that some of the proposals for 2014 that we do not support at this time *might* reduce year to year volatility. But we also recognize that they could increase volatility and hardship depending on the type of patients that a hospital serves.

For the 2014, the proposed payment rates cannot be compared with the current payment rates because of the major packaging changes that are proposed. Given the very significant changes in packaging, a meaningful comparison would require examining current versus proposed payments for an encounter, not for a service, but the proposed rule does not provide this information. Below we discuss the kind of information that we would like CMS to provide when these policies are re-proposed.

2. Packaging seven additional items and services; composite APCs

CHA does not support the proposals on expanded packaging and composite APCs, although we generally support larger payment bundles that give greater flexibility to hospitals and move away from micro-managing. While we are supportive of the concept of packaging, we believe that packaging needs to be done deliberately and only after careful analysis with the opportunity for public input informed by detailed information included in the proposed rule. We note that some services should not be packaged – for example, expensive and infrequently used items and services. If packaged, such items and services would add only a small amount to the payment rate, but a hospital serving a patient base that often required them would be inadequately paid for the services. Imbalances of this nature can harm both beneficiary access and hospitals. It is for this reason that we urge CMS to provide a much greater amount of impact information, including data on an encounter rather than individual service basis as well as showing how the impact varies by hospitals' patient mix and type of hospital.

CHA also notes that hospitals could, in theory, do this type of impact analysis on their own factoring in the nature of the patients they serve and conditions they treat. With the 2014 proposed rule, however, this has not been possible. Outside experts who have previously been able to replicate CMS' proposed rates were largely unable to do for this proposed rule. We believe this to be due to a combination of CMS errors in the proposed rates and a lack of transparency and detailed information needed to reproduce the rates. As noted, these gaps lead us to urge CMS not to implement the proposals in 2014.

CHA is concerned that the proposed packaging of add-on services could hurt hospitals providing a large volume of chemotherapy services, especially those providing services to a sicker patient population requiring longer infusion times. CMS' proposal would package the add-on hour of infusion time to the base infusion codes, which would overpay hospitals providing mostly shorter infusions while penalizing other hospitals. We are concerned that this proposal could harm beneficiary access to needed services while also financially disadvantaging the hospitals that provide the services. Similarly, we note packaging all skin substitutes could harm certain patients. While the proposed rule notes that there is wide variability in the cost of the products, the preamble fails to note whether any of the products might be used for patients

requiring more costly wound care. As with chemotherapy, such patients and the hospitals serving a disproportionate number of them would be harmed.

CHA also is concerned that the proposed packaging could increase beneficiary copayments because currently no coinsurance is applicable for lab services. While CMS acknowledges this as a potential issue in the proposed rule, it dismisses the issue with a statement that the agency believes on balance beneficiaries will face lower copayments. The proposed rule, however, presents no data or analysis to support this conclusion. This is another example of the lack of transparency in the proposed rule inhibiting the public's evaluation of important issues. CHA also notes that the increase in beneficiary copayments will lead to increased bad debt, which is not adequately reimbursed in Medicare to the detriment of hospitals.

Finally, CHA is concerned that CMS may have significantly under-funded the OPPS in its budget neutrality calculation. The proposed rule indicates that the costs of lab services previously paid under the lab fee schedule were added to the OPPS base in calculating the budget neutrality scaler. The proposed rule, however, provides no information concerning how this was done and no data to allow the public to review the determination of budget neutrality. In addition, CMS apparently did not add other amounts to the OPPS to account for the items and services that would be newly paid under the OPPS through the 29 comprehensive APCs. Durable medical equipment, therapy services, inpatient nursing services, and inpatient room and board for overnight outpatient stays would all be paid under the OPPS rather than under the separate fee schedules or systems through which they are currently paid. Yet, no funds are added to the OPPS for these categories.

3. Collapsing hospital visit codes

CHA opposes collapsing the multiple visit codes to one code each for clinic, Type A emergency department and Type B emergency department visits. We are concerned that moving to a single visit code could disadvantage certain types of patients and hospitals, especially with the combined impact of this change with the proposed new packaging. For example, it appears that rural hospitals could be significantly disadvantaged. Moving to a single visit code could also disadvantage hospitals treating a more severely ill patient population which often might require longer, more complicated visits. In addition, patients with longer, more complex visits are the patients that likely would require more diagnostic services, lab tests and other ancillary services that CMS proposes to package.

CHA's inability to support the proposal is based in part on the lack of sufficient information to thoroughly evaluate its implications. CHA is very concerned that the proposed rule does not provide any evidence that CMS examined the combined impact of these proposals on combined reimbursement of all of the services provided during actual patient encounters, as represented in claims data, for particular patients and the hospitals serving them. We strongly believe that analyses of this type must be performed before the proposals are finalized. Moreover, both the findings and the supporting data must be released to the public to allow for informed comment on the proposals during a public comment period.

We note that our concerns about errors in calculating the proposed rate for APC 0634, the single clinic visit, appear to have been addressed by CMS' recent data correction release. The original proposed rate was nearly 9 percent lower than the current rate for a mid-level clinic visit, the most common visit type, an unlikely outcome given the volume of the mid-level clinic visit and also considering the substantial new packaging that is proposed as well as the1.8 percent rate update.

4. Refinement of APC Weight Calculation

The proposed rule increases the number of cost to charge ratios (CCRs) used to convert charges to cost from the current 16 to 19 by adding new CCRs for Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and Cardiac Catheterization. **CHA supports use of the new CCR for cardiac catheterization and continued use of the CCR for implantable devices but *opposes* using the CCRs for MRI and CT**. Due to the way that many hospitals report and allocate the cost of expensive equipment like imaging equipment (for example, by square footage), the data in the new cost centers used to calculate the new CCRs do not capture all of the equipment cost of these imaging services. That is, not all of the costs of the equipment are reported in the relevant cost center but are spread across other cost centers. This causes the CCRs to be unrepresentative and leads to seriously underestimated costs for these services.

We urge CMS to examine the resulting costs with the new CCRs and to consider whether they appear credible. Because the costs of these expensive imaging services are calculated to be about the same as a simple x-ray of the comparable body area, we think CMS should conclude that the results are not credible and reject using these CCRs. We urge CMS not to change the CCR used for these services and to work with hospitals to improve how the costs of the relevant equipment are reported on the cost report so that the more detailed CCRs might be used in the future.

CHA is concerned about the impact of the change on the nation's trauma centers and tertiary hospitals because trauma patients and more severely ill patients frequently require significant imaging services. We also are very concerned about the negative impact that adopting the new CCRs would have on physician offices and free-standing imaging centers because reductions in the OPPS rates would carry over to these sites of service due to the cap established by the Deficit Reduction Act (DRA). Using the new CCRs to set the OPPS rates would have much greater deleterious consequences than their use in the IPPS because the OPPS sets rates for individual services not for a DRG package of services and because of the DRA spillover. The proposed policy is not appropriate or sensible because it would lead to significant overpayments for simple imaging services like x-rays while significantly underpaying for the more costly services.

5. Separately Payable Drugs

CHA supports the proposal to continue to reimburse separately payable drugs at the statutory default rate of ASP+6%. We believe that the methodology CMS had used

previously to establish the payment rate for these drugs had become increasingly complex over recent years and we applaud CMS for recognizing the problems with the previous approach. Using the statutory default rate will provide predictability to hospitals concerning the reimbursement level for these drugs.

6. Device to Procedure and Radiopharmaceutical to Procedure Edits

CMS proposes to eliminate the claims edits used by Medicare contractors and to end the practice of returning claims which fail edits to the hospital. CHA does not oppose this change, but **CHA does oppose dropping the edits in selecting the set of claims to be used to calculate geometric mean costs of services.** While ending the contractor edits may reduce burden on both hospitals and contractors, dropping the claims processing edits does not reduce burden and would lead to less accurate and appropriate geometric mean costs. If CMS finalizes the proposal to end the practice of returning claims, it should ensure that all relevant cost are included in the claims used for rate setting. We oppose making a change that reduces payment accuracy.

7. Inpatient Only Procedures

CHA continues to urge CMS to eliminate the inpatient only 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 OPPS. There are numerous problems created by the inpatient list as has been documented in past comments. The biggest continuing problem is that the 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 importance of establishing a Medicare policy that reflects reality wherein 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 has not solved 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.

If CMS retains 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.

8. Physician Supervision

CHA strongly opposes CMS' proposal to end the non-enforcement policy for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals. We again urge CMS to rescind the direct supervision policy in favor of an approach that would make general supervision the default supervision level and use the review process to identify specific procedures which should be subject to a direct supervision requirement.

We continue to be particularly concerned about the implications of CMS' approach to direct supervision on small, rural and critical access hospitals, which already are struggling with significant provider shortages. **CHA draws your attention to the comments from rural providers which indicate that the lack of qualified personnel in rural areas makes it difficult to staff physicians or non-physician practitioners (NPPs) for supervision purposes.** The comments by rural providers speak to their unique challenges serving their respective rural communities. We recommend that CMS immediately undertake a study of the unintended consequences that likely will arise from the application of the new supervision rules for outpatient services in small rural hospitals and CAHs and to continue the current enforcement moratorium at least until that study is completed and its results reflected in policy.

Direct supervision would require that a physician or non-physician practitioner (NPP) be "immediately available and interruptible" when outpatient therapies such as drug infusions are provided to outpatients. Recruitment of physicians to CAHs already is very difficult and the few available physicians and NPPs have heavy workloads seeing patients. Adding to their workloads or trying to recruit additional practitioners to meet the direct supervision requirement may not be feasible at many CAHs. The skills of their limited numbers of physicians need to be focused on taking care of patients, not monitoring well-trained nurses who have for a long time professionally handled these outpatient therapies on a daily basis with no significant quality or safety issues. Enforcement of the direct supervision requirement will force curtailment of many outpatient therapies at CAHs and reduce access for rural populations.

The COPs for CAHs require that a physician or NPP be available within 30 minutes of being called for an emergency. The direct supervision rule requires a more immediate presence of a physician or NPP for outpatient services than what is required in an emergency. The requirement undermines the CAH program that was designed to maintain access to health care services in rural areas and keep rural hospitals from closing. Patients treated in CAH outpatient settings generally have low acuity conditions. Seriously ill patients would have already been admitted as inpatients or shipped to larger tertiary care hospitals.

CMS's justification for starting to enforce the direct supervision requirement in CAHs is that it has created a process, using the Advisory Panel on Hospital Outpatient Payment (HOP), under which hospitals may request a change from direct supervision to general supervision for a specific code on a code-by-code basis. Several of our member systems have utilized the process but found that their concerns were not adequately addressed by this process. For example, the HOP panel recommended general supervision for 11 separate codes that were presented by CHI, but CMS accepted only 5 of the recommendations. In addition to CMS not following the Panel's recommendations, the HOP panel process is not adequate for CAHs because CMS policy does not allow the panel to recommend policy changes that would create different supervision standards for CAHs. If the HOP panel approves a change in supervision level for a code and CMS accepts it, the supervision level must be changed for every hospital, including large tertiary hospitals that treat critically ill patients. CAH strongly believes that CMS must create targeted policies that address the specific needs of rural communities and patients residing there rather than using a one size fits all policy driven by the practice of medicine in urban centers.

CHA strongly urges CMS, at a minimum, to drop the direct supervision requirement for these five intravenous infusion services at least when the services are provided in CAHs. These are among the codes which were previously presented to the HOP panel and the Panel recommended general supervision for them but CMS rejected the Panel's recommendations. The five codes are:

- CPT code 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour.
- CPT code 96367: Intravenous infusion, for therapy, prophylaxis, or diagnoses (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (list separately in addition to code for primary procedure).
- CPT code 96368: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (list separately in addition to code for primary procedure).
- CPT code 96374: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); Intravenous push, single, or initial substance or drug).
- CPT code 96375: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (list separately in addition to code for primary procedure).

To reiterate, CHA is especially concerned about the potential serious consequences of direct supervision requirements on rural oncology services. **We strongly advise CMS to modify the clinical review criteria used to assess appropriate supervision levels in order to give**

consideration of the different environments in which the services will be provided and the challenges faced in rural communities.

9. Hospital Outpatient Quality Reporting (OQR) Program; Ambulatory Surgical Center Quality Reporting (ASCQR) Program

CHA supports the proposed removal of two measures from the OQR program beginning with the FY 2016 payment determination. Data collection was already delayed for these measures (OP-19: Transition Record with Specified Elements Received by Discharged Patients and OP-24 Cardiac Rehabilitation Patient Referral from an Outpatient Setting) while specifications were reviewed. Now that CMS has concluded that these measures cannot be adequately specified for the outpatient setting, it is appropriate that they be removed from the measure set. In the future, CMS should ensure that measure specifications are defined and tested before measures are finalized for the OQR program.

In addition, CHA recommends that CMS act to remove of OP-22: Patient Left without Being Seen. The Measures Application Partnership (MAP) has recommended removal of this measure because it has lost its National Quality Forum (NQF) endorsement.

CHA supports the use of a measure of influenza vaccine coverage among healthcare personnel. Such a measure has already been adopted for the inpatient hospital and ambulatory surgical center quality reporting programs, and it is appropriate to also include it as part of the OQR program measure set to the extent necessary to ensure that all hospital personnel are covered. However CHA urges CMS to ensure that the separate IQR and OQR measures do not operate in a way that would cause a hospital that somehow fails to report on the measure to face a 2% update penalty on both inpatient and outpatient reimbursements

CHA does not support the addition of any of the four other measures proposed for inclusion in both the OQR program and the ASCQR program beginning in 2016. CHA supports the effort to align OQR and ASCQR program measures. However the proposed measures are not appropriate to add to the two programs at this time. The proposed measures were developed as tools for assessing individual physician performance, and none of them has been specified for the outpatient facility setting. The only one fully endorsed by the NQF, improvement in visual function 90 days after cataract surgery (NQF#1536) involves a patient survey. Issues regarding the sample size and the fielding of the survey, which are currently built around the Physician Quality Reporting System, would have to be resolved before this measure could be tested in a facility setting. The measure assessing complications following cataract surgery (NQF #0564) would have to be re-specified to take into account that patients may not return to the facility for follow-up care. Such care might occur in the surgeon's office or in another facility. Similarly, in the case of the two colonoscopy measures which assess the interval between procedures, it would be difficult for a hospital to know how long it has been since a patient had a colonoscopy if the individual had the procedure in another setting. These are not

minor issues, and they need to be carefully resolved and the facility-based measure specifications tested in facility settings before these measures are added to the OQR program.

10. Hospital Value-Based Purchasing (VBP) Program

CHA supports the proposed independent CMS review process that CMS proposes to make available to hospitals that are dissatisfied with the result of the appeal process already in place for the VBP program. The VBP payment adjustment is a significant part of the IPPS and it is appropriate to give hospitals additional recourse if they believe the adjustment has not been properly calculated.

In closing, thank you for the opportunity to share these comments in regard to the proposed CY 2013 OPPS rule. We look forward to working with you on these and other issues that continue to strengthen the country's hospitals and health care system. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

Michael Rodgers
Senior Vice President
Public Policy and Advocacy