September 2, 2014

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

RE: CMS-1613-P, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals: Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors: Appeals Process for Overpayments Associated With Submitted Data; Proposed Rule (Vol. 79, No. 134), July 14th, 2014

Dear Ms. Tavenner:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay, rehabilitation, and long-term care hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services. The FAH appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the above notice of proposed rulemaking ("Proposed Rule"), published in the Federal Register (79 FR 40916) on July 14, 2014. We also include comments on the new Level II HCPCS codes introduced July 1, 2014 and identified as eligible for comment during the CY 2015 OPPS/ASC proposed rule comment period.

Our comments address these areas:

Procedures Affected By Proposed Comprehensive APC Policy; Proposed Complexity Adjustment

➢ The FAH has identified a class of significantly disadvantaged services and recommends two changes for the final rule.
The FAH urges CMS to monitor and report on the impact of this major change before proposing any expansion of the policy.

Relationship of OPPS And ASC Payment Rates For Device-Dependent APCs

The FAH has concerns about the impact of the comprehensive APC policy on OPPS versus ASC payment differences and recommends that CMS make changes to preserve the current relationship.

The FAH urges CMS to bring the ASC payment software up to date so that it can accommodate the new directions characteristic of OPPS policy, such as comprehensive APCs and conditional packaging.

Claims Processing Edits For Device-Dependent Procedures

The FAH has technical concerns with CMS’ proposal and recommends that CMS dispense with all such claims processing edits.

Packaging Of Ancillary Services, Prosthetic Supplies And Additional Add-On Codes

The FAH supports the proposal but strongly urges CMS to monitor and report on its impact before raising the $100 threshold or otherwise expanding the scope of the policy.

Policies Pertaining To The Creation Of G Codes For New And Revised CPT Codes That Are Effective January 1

The FAH opposes the proposed use of G codes because of the burden they would place on hospitals and physicians and the potential for confusion. We believe the proposal violates CMS rules and procedures pursuant to HIPAA.

Proposed Payment For Partial Hospitalization

The FAH is very concerned that the proposed 11-15% reductions in partial hospitalization payment rates would jeopardize beneficiary access to critically important, intensive psychiatric services.

The FAH recommends that CMS freeze CY 2015 payment rates at CY 2014 rates to stabilize the payment system and allow for further investigation into the drivers of the payment fluctuations.

Data Collection Pertaining To Services Delivered By Off-Campus Provider-Based Departments

CMS proposes to begin collecting data on services furnished in off-campus provider-based departments beginning in 2015 by requiring hospitals and physicians to report a modifier for those services furnished in an off-campus provider-based department on both hospital and physician claims.

The FAH recommends a 1-year delay in the implementation of this requirement until it can work with hospitals and other affected stakeholders to develop a more tailored plan that collects only the data needed as a basis for Medicare payment accuracy.

Hospital Outpatient Quality Reporting Program Updates

The FAH recommends removal of measures OP-15 (Use of Brain CT for Atraumatic Headache) and OP-31 (Cataracts-Improvement in Patient’s Visual Function within 90 Days following Cataract Surgery) from the OQR. Neither measure is appropriately
specified for the outpatient setting. The data collection and reporting previously has been deferred on both measures.

- The FAH recommends following the recommendations of the Measure Applications Partnership (MAP) to remove several additional measures OP-14 (simultaneous Use of brain CT and sinus CT), Op-20 (Door to Diagnostic evaluation), OP-22 (left Without Being Seen), and OP-25 (Safe Surgery Checklist).

- The FAH does not support the addition of OP-32 (Facility Seven Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy) for CY 2017 payment determinations. Among other concerns, the proposed measure is not NQF endorsed, and the FAH is concerned about the measure’s reliability as currently specified.

Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

- The FAH strongly urges CMS to remove ASC-11 (Cataracts – Improvement in Patient’s Visual Function within 90 days Following Cataract Surgery) for the same reasons the FAH believes the measure should not be included in the OQR.

- The FAH strongly recommends the development of an ASCQR data validation program. The value of public reporting depends on the accuracy and integrity of the data that is submitted.

Proposed Revision of the Requirements For Physician Certification Of Hospital Inpatient Services Other Than Psychiatric Inpatient Services

- The FAH applauds CMS for removing the certification requirement for stays less than 20 days. We agree with CMS that requiring the certification does not outweigh the associated administrative requirements placed on hospitals. CMS also should affirm that verbal inpatient admission orders must be authenticated within a reasonable time, but need not be done so prior to discharge, which is consistent with existing policy for all other types of verbal orders.

CMS-Identified Overpayments Associated With Payment Data Submitted By Medicare Advantage (MA) Organizations And Medicare Part D Sponsors

- The FAH recommends that any ‘look-back’ period associated with CMS-identified payment errors only be applied going forward.

- The FAH urges CMS to ensure any associated provider record requests are limited to the specific instance of erroneous data under dispute.

Drugs & Biologicals

- Responding to the comment period on new level II HCPCS codes implemented in July 2014 (79 FR 40975), The FAH recommends a change in the units specified in the code description for HCPCS code C9134 to conform to the units specified for similar drugs.

- The FAH recommends inclusion of additional HCPCS codes to which the CY 2015 drug-specific packaging determination methodology would apply.
PROCEDURES AFFECTED BY PROPOSED COMPREHENSIVE APC POLICY; PROPOSED COMPLEXITY ADJUSTMENT

In the 2014 final OPPS rule, CMS finalized a proposal, with a delayed January 1, 2015 effective date, to create 29 comprehensive APCs to replace 29 of the 39 existing device-dependent APCs with new APCs that would prospectively pay for 167 of the most costly device-dependent services. A comprehensive APC (C-APC) is a new classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS calculates a single payment for the entire hospital encounter, defined by a single claim, regardless of the date of service span on the claim.

For 2015, CMS proposes several additional C-APCs, including some lower cost device dependent APCs not proposed last year and 2 new APCs for other procedures and technologies that are either largely device dependent or represent single session services with multiple components. CMS also proposes to restructure and consolidate the current 39 device dependent APCs, resulting in a total of 26 C-APCs for them in 2015.

The FAH commends CMS for the changes proposed in C-APC policies for 2015, especially the significantly revised complexity adjustment. Generally, the changes are very responsive to the comments received on the 2014 interim final rule and ameliorate negative effects on hospitals. The FAH recommends additional changes in the C-APC proposal for 2015 and, with those changes, we would support the C-APC policy for implementation in 2015.

Expansion of C-APCs to lower cost services. The FAH has serious concerns about the significant potential for inadequate hospital payment as a result of the combined effect of the all-encompassing packaging policies and the proposed expansion of C-APCs to all device-dependent APCs as well as to two additional APCs. Expanding the C-APC policy in this manner results in a lower cost group of services being treated as C-APCs, compared to the FY 2014 proposal when the policy applied only to 29 of the 39 device-dependent APCs, mostly ones involving high cost devices. Five of the 28 C-APCs proposed for 2015 have a payment rate under $3,500.

The expansion to lower cost C-APCs and the C-APC packaging policies lead to a large number of cases where a non-J1 procedure from a relatively high paying APC is performed with and packaged into a lower paying C-APC. For example, C-APC 0622, Level II Vascular Access Procedures, with a payment rate of $2,517.04, includes catheter procedures such as CPT 36561 and CPT 36558. These low-paying catheter procedures for placement of a central line (e.g., for drugs, chemotherapy agents, total parenteral nutrition) are placed in patients for many reasons, including a patient requiring IV therapy following a surgical procedure.

For example, if a patient has a malignant tumor removed (status indicator T procedure) and will require chemotherapy after a period of recovery, the physician may place a central line before the patient is discharged from the hospital following the surgical procedure. Level II Vascular Access Procedures is a service that may be performed with higher paying surgeries, yet under the proposed C-APC policy the hospital would be paid only $2,517.04 for the vascular access procedure and nothing for the higher paying surgery. We further note that while placement of the central line is related to the patient’s condition, it is clearly not related to the...
surgical procedure of removing the tumor. Furthermore, this situation is akin to our and other commenters’ objections to the 2014 ancillary packaging proposal: that expensive procedures provided to a relatively small proportion of the patients receiving the service designated as primary for payment purposes do not add a sufficient amount to the payment, when averaged over all patients, to cover the additional cost of the patients getting the service.

Three APCs in particular are characterized by a high percentage of cases in which a non-J1 procedure on the claim has a higher payment than the J1 procedure: APCs 0652 (Insertion of Intraperitoneal and Pleural Catheters), 0427 (Level II Tube or Catheter Changes or Repositioning), and 0622 (Level II Vascular Access Procedures). The respective percentages of such cases for the three C-APCs are about 7.2%, 5.4%, and 4.8%.

The FAH strongly believes that CMS must address this problem in the final rule and recommends three options for CMS consideration. Under the first two options, CMS always would identify the higher paying procedure as the primary service and would make a separate payment for that service even if another procedure on the claim has status code J1. In option 1, CMS simply would exempt the primary service from being packaged with the C-APC payment.

Under the second option, CMS also would identify the higher paying procedure as the primary service and would base payment on that service. CMS would apply the multiple procedure discount policy (if the primary service has status indicator T and not S) and pay for second and subsequent procedures at 50 percent of the APC rate. Other services on the claim (other than the primary service and the J1 service) might be packaged with, and paid as part of, the C-APC consistent with the structure of C-APCs.

Under the third option, CMS would revise the scope of the C-APC policy to limit C-APCs to only high payment services that are rarely performed in conjunction with other procedures with a higher payment. In contrast, the low payment C-APCs that CMS proposes to add in 2015 include many supportive services that are likely to be performed either individually as a minor procedure or in conjunction with a more significant “T” procedure as a supportive or conjunctive procedure. The FAH does not believe that these types of procedures are appropriate for the C-APC methodology unless one of the first two options is adopted in the final rule.

Span of days included in C-APC. The FAH also is concerned about the long span of days included in many C-APC claims, sometimes exceeding 30 days. We find from analysis of the 2013 claims data that more than 2.6% of C-APC encounters include services spanning a period longer than 5 days. Three APCs in particular stand out: C-APCs 0067 (Single Session Cranial Stereotactic Radiosurgery), 0425 (Level V Musculoskeletal Procedures Except Hand and Foot), and 0648 (Level IV Breast and Skin Surgery) having 6%, 4% and 3%, respectively, of their costs on day 3 or later. The longer the period elapsed since the date of the primary procedure, the more likely it is that the other services are unrelated to the primary service. Packaging these unrelated services will reduce the homogeneity of the claims included in the C-APC and the clinical cohesiveness of the C-APC. Basing payment on such a poorly structured C-APC likely would lead to inadequate hospital payment for the particular cases having a long span of time coupled with higher than necessary payment for the other cases in the C-APC. The FAH recommends that CMS limit the services included in the C-APC to services that are provided on the day of the J1 procedure or one day following the day of the J1 service, and to services provided
prior to the J1 procedure during the same hospital encounter.

Future expansion of C-APCs. Adoption of C-APCs is major change for the OPPS, fundamentally restructuring payment policies for a large portion of the OPPS. The FAH strongly urges CMS to monitor and report on the impact of this major change before proposing any expansion of the policy.

RELATIONSHIP OF OPPS AND ASC PAYMENT RATES FOR DEVICE-DEPENDENT APCS

Because a C-APC would treat all individually reported codes as components of the comprehensive service, the OPPS proposal would make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS notes that the OPPS claims processing system can be configured to make a single payment for the comprehensive service whenever a HCPCS code that is assigned to a comprehensive APC appears on the claim. The ASC claims processing system, however, cannot accommodate this level of complexity.

Therefore, CMS proposes that all separately paid ancillary services provided integral to surgical procedures that map to a C-APC would continue to be separately paid under the ASC payment system instead of being packaged into the payment as they are for the comprehensive APC under the OPPS. The ASC payment rates for these C-APCs would be based on the 2015 OPPS relative payment rates calculated using the standard APC rate setting methodology for the primary service rather than using the relative payment weights based on the C-APC weights under the OPPS. CMS also proposes to use the standard OPPS APC rate setting methodology to calculate the device offset percentage for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs.

The FAH is concerned that this divergence of OPPS and ASC policy and payment methodology will cause distortions in the relative payment relationship between ASCs and hospital outpatient departments. In some cases, ASCs could be paid more in absolute dollars than a hospital would be paid under the OPPS for the same service.

Generally, ASCs are paid roughly 60% of the OPPS rate. As the imbedded chart shows, a large number of cases would have an ASC payment rate of 80% or more of the OPPS rate under the policies in the OPPS/ASC proposed rule. Analysis by the Moran and Watson companies finds that 16 of 26 APCs commonly performed in both the outpatient and ASC settings have a mean ASC payment level that is 80% or more of the corresponding mean OPPS payment level. These 16 APCs represent almost one-third of
total cases in the 26 C-APCs (227,056 out of 717,874 cases).

The FAH believes this could have a major effect on hospitals as cases may shift from one setting to another in response to financial incentives to direct patients to one setting or another based on what is expected to be performed. Certain types of cases will be moved to the ASC, while other types will be moved to the outpatient department.

The FAH believes that one factor of the change in relative payments might be the procedure used by CMS to calculate the ASC rates. Specifically, CMS first grouped the affected cases into their appropriate C-APCs using the C-APC group assignment logic. To determine the ASC rate, CMS calculated what the OPPS payment would be under the old OPPS policy, before C-APCs. Thus, these payment rates are calculated without the extensive packaging of C-APCs. CMS, however, did not return the non-packaged services to what their APC assignment and payment status would have been before C-APCs. In effect, these services, which are packaged in the C-APC methodology, disappear from the calculation of relative weights under the “old” methodology used for the ASC rates. These packaged services are included in the OPPS weight calculation for the C-APCs and therefore they do not affect the OPPS weight calculation for the other APCs. The ASC rates are based on the OPPS weights for the other APCs combined with a special OPPS weight calculation for the device-intensive procedures. The FAH is concerned that the mixed methodology may contribute to the shift in relative payment amounts among the two systems.

The FAH urges CMS to correct this flawed methodology for the final rule by determining a **complete set of OPPS rates under the old, pre-C-APC methodology** rather than combining two different OPPS weight calculation methodologies to determine the ASC rates, with the device-intensive ASC weights based on OPPS weights using the old methodology and the other ASC weights being based on the actual 2015 OPPS weights in a scheme employing the C-APC methodology.

For the future, the FAH urges CMS to bring the ASC payment software up to date so that it can accommodate the new directions characteristic of OPPS policy, such as **comprehensive APCs and conditional packaging**. The statute requires that the ASC payment system be based on the OPPS and we are concerned that the payment systems are diverging, and will continue to do so, unless the ASC software gains the capability to replicate the OPPS payment logic.

**CLAIMS PROCESSING EDITS FOR DEVICE-DEPENDENT PROCEDURES**

The FAH does not support CMS’ proposal to create claims processing edits that require *any* of the device codes used in the previously employed device-to-procedure edits to be present on the claim whenever a procedure code assigned to one of the 26 proposed comprehensive APCs listed in Table 5 of the proposed rule is reported on the claim. Table 5 is a list of the 26 proposed 2015 C-APCs of the total 28 C-APCs that CMS previously recognized as device-dependent APCs.
Eleven of the 26 C-APCs for which CMS would require a device code to be present include procedure codes which do not have current device edits. And of 258 procedures assigned to these 26 C-APCs, 106 procedures, or 41%, do not have current device edits. Codes not requiring edits include HCPCS that may describe a revision procedure which does not involve use of a device as well as other procedures where no device code exists to describe the type of item used in the procedure. We note that only devices which have qualified for pass through status in the past have HCPCS codes. Items that have never met the pass-through device criteria do not have HCPCS codes so many of these procedures do not have a code that would always be available to report the specific item used in the procedure.

Given this situation, requiring a device code to be present whenever a procedure code assigned to one of the 26 identified C-APCs is billed would be confusing and problematic for hospitals. Therefore, the FAH recommends that CMS eliminate all such claims processing edits. We note, as CMS itself noted in 2014 OPPS rulemaking, that hospitals have had years of experience reporting the device codes with the procedure, making the edits unnecessary.

PACKAGING OF ANCILLARY SERVICES, PROSTHETIC SUPPLIES AND ADDITIONAL ADD-ON CODES

The FAH supports the expanded packaging proposed by CMS for 2015 and we commend CMS for its re-crafting of the 2014 ancillary packaging proposal to create a revised proposal that raises fewer issues for hospitals and beneficiaries. We believe that the 2015 proposal is responsive to concerns raised by the FAH. We are, however, concerned about CMS’ suggestion that it is likely to expand ancillary service packaging in future years. The proposed rule would extend packaging only to include ancillary services with a mean cost of less than $100. In addition, CMS would package all prosthetic supplies and most add-on codes in 2015.

Although the FAH is generally supportive of packaging, we wish to emphasize that packaging decisions must be considered cautiously and 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 services to these patients. Imbalances of this nature can harm both beneficiary access to important services and the hospitals that do serve them.

It is for this reason that we oppose expansion of the packaging of ancillary services to services with mean costs greater than $100. We believe that the 2015 proposal to package only lower cost ancillary services addresses our concerns about hospital impact and beneficiary access, but we are troubled by the clear indication in the proposed rule of CMS’ intention to expand ancillary packaging in future years. We ask CMS to reconsider further packaging.

We also urge CMS to provide a much greater amount of impact information on its packaging proposals, including data on a hospital encounter rather than only on an individual service basis. We request that the public be provided information showing how proposals’ impacts vary by hospitals’ patient mix and type of hospital. In the 2015 proposed rule, for example, very little information is provided on the proposal to package all prosthetic supplies.
The rationale given in the proposed rule is inadequate because the agency argues for a policy to package prosthetic supplies used in conjunction with implanted prosthetics, stating that the non-implantable prosthetic supplies are integrally related to the implanted portion and part of the full service. Then, however, the proposed rule merely states that the agency believes that all prosthetic supplies should be packaged as medical supplies. Regarding the expansion to all prosthetic supplies, the proposed rule provides the public with no information about what supplies would be affected and what the impact of packaging them would be.

The FAH supports the proposals to expand packaging but we strongly urge CMS to monitor and report on the ancillary packaging proposal’s impact before considering an increase of the $100 threshold or otherwise expanding the scope of the policy.

The FAH also supports CMS’ proposal to continue to exclude chemotherapy services from the proposed expansion of packaging of add-on services.

POLICIES PERTAINING TO THE CREATION OF G CODES FOR NEW AND REVISED CPT CODES THAT ARE EFFECTIVE JANUARY 1

For new and revised CPT codes that are not received early enough in the CMS rate setting process for CMS to propose APC and status assignments in the OPPS proposed rule for a year, CMS proposes to create and use Level II HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until CMS could include proposed assignments in the following year’s proposed rule.

CMS provides the example of a single CPT code separated into two new CPT codes that the agency did not receive until May 2015. Under the proposed process, CMS would assign each of the new CPT codes to status indicator “B” (Non-allowed item or service for OPPS) and create a single G-code with the same description as the single predecessor CPT code, and continue to use the same APC and status indicator assignments for that code during the year. CMS would propose status indicator and APC assignments for the two new CPT codes during rulemaking in 2016 for payment beginning in 2017. CMS acknowledges that the use of HCPCS G-codes may place an administrative burden on providers billing for services under the OPPS and ASC payment system.

The FAH appreciates CMS’ recognition of the concern raised by several stakeholders, including hospitals, specialty societies, and others regarding the process CMS currently uses to recognize new and revised CPT codes. The current process, in which payment decisions pertaining to these codes are promulgated in an interim final rule, does not provide an opportunity for public comment prior to the January 1 implementation date of the rule.

Nevertheless, the FAH strongly opposes the proposed creation and use of G codes. We urge CMS to work with the AMA to develop a revised process and timeline that 1) maintains the opportunity for consultation during the AMA’s CPT and RUC processes and 2) allows CMS to use notice and comment rulemaking before the new or revised codes and payment factors take effect.
The FAH is greatly concerned about the burden and confusion that the G codes would create for hospitals, physicians and others. Other payers most likely would use the new and revised CPT codes, which of course, are the HIPPA standard. We note that Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. These statements are from the HCPCS coding guidelines established by CMS and described in the document, “Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures,” revised September 6, 2012:

- The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not identified by the HCPCS level I, CPT codes.
- The G codes are used to identify professional health care procedures and services that would otherwise be coded in CPT-4 but for which there are no CPT-4 codes.

These statements clearly indicate that Level II HCPCS codes are intended for two purposes: 1) for health care equipment and supplies in health care transactions that are not identified by the HCPCS level I, CPT codes and 2) to identify professional health care procedures and services that would otherwise be coded in CPT-4 but for which there are no CPT-4 codes. The FAH strongly believes that the proposed change for delaying adoption of new and significantly revised CPT codes for one year and replacing them with level II HCPCS codes goes against the spirit and purpose of standard transactions, and may violate statutory and regulatory requirements.

PROPOSED PAYMENT FOR PARTIAL HOSPITALIZATION

The partial hospitalization program (PHP) is a critical component of Medicare’s mental health benefit that provides beneficiaries experiencing acute mental illness with access to intensive outpatient treatment. Prior to the advent of this benefit, individuals were limited to either inpatient psychiatric hospital care, or much more limited outpatient office-based visits. The partial hospitalization benefit fills the need for an appropriate level of care for beneficiaries suffering mental illness. It establishes an alternative to inpatient hospitalization that still provides beneficiaries with the more intensive services unavailable from an office-based visit. Today, the partial hospitalization benefit is an essential part of the care continuum for Medicare beneficiaries that allows them to receive the most appropriate level of services delivered in the most cost-effective way for the Medicare program.

Given the importance of the partial hospitalization benefit to the care continuum that supports individuals experiencing a mental health crisis, it is imperative that beneficiaries have access to these services. Individuals receiving partial hospitalization services suffer from serious, acute psychiatric conditions and require levels of care that would otherwise require inpatient hospitalization, which may be in the best interests of neither the patient, nor the program. Of even greater concern is the possibility that, absent access to the partial hospitalization benefit, acutely ill Medicare beneficiaries may be forced to seek care through hospital emergency departments, or forego necessary treatment.
Beneficiary access to partial hospitalization services requires a stable payment system with adequate payment rates. The FAH is therefore very concerned by the Proposed Rule’s recommendation to significantly cut CY 2015 payment rates for both hospital based and community health center (CMHC) partial hospitalization programs. As acknowledged in the Proposed Rule, the factors driving these destabilizing rate reductions are unclear, however, the real and serious risks to beneficiary access are very clear. In fact, as further discussed below, access to PHP is already at risk as there has been a dangerous decline in PHP services in recent years. The FAH therefore recommends that CMS freeze CY 2015 partial hospitalization rates at CY 2014 levels until the drivers leading to fluctuations in per diem payment amounts are better understood.

The Proposed Payment Rate Reductions for CY 2015 Would Further Jeopardize Access

The Proposed Rule recommends CY 2015 payments rates for hospital-based and CMHC payment rates that are significantly below CY 2014 level, as shown below:

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015 (proposed)</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital-Based</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0175 Level I PHP (3 services)</td>
<td>$190.15</td>
<td>$169.36</td>
<td>-10.9%</td>
</tr>
<tr>
<td>0176 Level II PHP (4+ services)</td>
<td>$213.64</td>
<td>$181.66</td>
<td>-14.9%</td>
</tr>
<tr>
<td><strong>Community Mental Health Centers</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0172 Level I PHP (3 services)</td>
<td>$99.04</td>
<td>$93.06</td>
<td>-6.03%</td>
</tr>
<tr>
<td>0173 Level II PHP (4+ services)</td>
<td>$111.73</td>
<td>$109.77</td>
<td>-1.75%</td>
</tr>
</tbody>
</table>

The FAH is deeply concerned that rate reductions of this level pose serious risks to beneficiary access to care. This risk is particularly true for hospital-based PHPs that are facing rate reductions of 11-15% in FY 2015. Significant rate reductions and unpredictable variations in payment rates year to year create serious financial stress on providers potentially leading to forced reductions, including eliminations, of needed PHP services. CMS itself acknowledges that payment stability matters.

“The CY 2015 proposed geometric mean per diem costs for hospital-based PHPs calculated under the proposed CY 2015 methodology using CY 2013 claims data show more variation when compared to the CY 2014 final geometric mean per diem costs for hospital-based PHPs. We understand that having little variation in the PHP per diem payment amounts from one year to the next allows providers to more easily plan their fiscal needs.” (emphasis added)

In fact, evidence already indicates that access to services is at risk. As demonstrated through research conducted by Dobson|DaVanzo & Associates, LLC (“Dobson|DaVanzo”) for
the National Association of Psychiatric Health Systems and the American Hospital Association, there has been a significant decline in PHP services in recent years. Table 2 below highlights that there has been a 60.2% decline in total PHP days of service over the period 2010-2013, with PHP days of service declining from 1,663,743 in 2010 to 661,122 in 2013.

Table 2: PHP Days of Service Over the Period 2010-2013

<table>
<thead>
<tr>
<th></th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>% change 2010-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Days PHP</strong></td>
<td>1,663,743</td>
<td>1,270,727</td>
<td>861,583</td>
<td>661,122</td>
<td>-60.2%</td>
</tr>
<tr>
<td><strong>Hospital-Based</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0175 Level I PHP (3 services)</td>
<td>67,834</td>
<td>64,046</td>
<td>67,326</td>
<td>65,245</td>
<td></td>
</tr>
<tr>
<td>0176 Level II PHP (4+ services)</td>
<td>271,058</td>
<td>443,820</td>
<td>466,192</td>
<td>451,034</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>338,892</td>
<td>507,866</td>
<td>533,518</td>
<td>516,279</td>
<td>+52.3%</td>
</tr>
<tr>
<td><strong>CMHC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0175 Level I PHP (3 services)</td>
<td>28,692</td>
<td>24,505</td>
<td>13,843</td>
<td>10,508</td>
<td></td>
</tr>
<tr>
<td>0176 Level II PHP (4+ services)</td>
<td>1,296,159</td>
<td>738,356</td>
<td>314,222</td>
<td>134,335</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>1,324,851</td>
<td>762,861</td>
<td>328,065</td>
<td>144,843</td>
<td>-89.06%</td>
</tr>
</tbody>
</table>

As overall PHP days of service have decreased, hospital-based PHP services have increased by 52.3%, helping to offset the dramatic decline in CMHC provided services. Without this increase in services by hospital-based PHPs, beneficiaries would face even greater difficulties accessing care. It is important to note, also, that the increase in hospital-based care has occurred in the higher acuity service levels, demonstrating that hospital-based providers are serving the most vulnerable and most complex patients. Maintaining access to hospital-based providers that are providing the majority of the PHP care will be critical going forward, and the proposed cuts could jeopardize this access.

The impact of inadequate payment for hospital-based PHPs has been recognized by CMS in the past:

[From CY 2011 OPPS/ASC final rule] “We are also concerned that paying hospital-based PHPs at a lower rate than their cost structure reflects could lead to hospital-based closures and possible access problems for Medicare beneficiaries because hospital-based PHPs are located throughout the country and, therefore, offer the widest access to PHP services.”

Given the risk to beneficiary access from significant rate cuts and an unstable payment system, the FAH urges CMS to freeze CY 2015 rates at the CY 2014 level. This action will provide
payment stability to PHP providers in order to protect beneficiary access, while also allowing CMS and the industry more time to develop a clearer understanding of the drivers leading to the PHP rate reductions, as discussed below.

The Factors Driving the PHP Rate Reductions Are Not Well Understood

In its discussion, CMS acknowledges that a number of factors (outlined below) could cause the fluctuations in the per diem payment amount. However, as discussed below and illuminated in the Dobson|DaVanzo analysis, research indicates that these factors are not, in fact, driving the payment fluctuations:

- **Establishing separate APCs and associated per diem payment rates for CMHCs and hospital-based providers based on provider type’s costs** – This has been in place since 2012 and therefore should not impact CY 2015 rates.

- **Basing relative payment rates on geometric mean costs** – This change occurred in CY 2014 and should not affect CY 2015 rates.

- **Provider-driven changes** – According to the Dobson|DaVanzo study, the mix of services has not changed from 2012 to 2013. In addition, the patient population being served has not changed, and 75% of primary diagnoses continue to fall into the categories of mood disorders and schizophrenia.

The above information highlights that the actual drivers leading to the fluctuations in costs are not well understood. Further research will be needed to develop a full understanding of these changes, including an examination of some of the other potential causes of fluctuations, including:

- Shifts of services from CMHCs to hospital-based PHPs;
- Shifts in the mix of provider within categories;
- The introduction of other types of hospitals offering PHP services; and
- Volume or other shifts.

**Given the lack of clarity regarding these fluctuations in costs, coupled with the threats to beneficiary access, the risk of implementing 11-15% rate cuts to hospital-based PHP services is too great, and CMS should instead freeze CY 2015 rates at the CY 2014 level.**
The Change Between the Geometric Mean and the Proposed Payment Rate is Higher Than in Previous Years

As CMS considers the potential impact of the proposed payment reductions, the FAH would also like to highlight the impact of the change between the geometric mean and the proposed payment rate. As identified in the work by Dobson|DaVanzo, the change is the highest in four years:

<table>
<thead>
<tr>
<th>CY</th>
<th>% Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>0%</td>
</tr>
<tr>
<td>2013</td>
<td>-2.8%</td>
</tr>
<tr>
<td>2014</td>
<td>-0.4%</td>
</tr>
<tr>
<td>2015</td>
<td>-4.5%</td>
</tr>
</tbody>
</table>

The proposed -4.5% adjustment for PHPs in CY 2015 explains almost one-third of the proposed PHP rate reductions. While we recognize that the adjustment is a way to calibrate the APCs so that the OPPS payment system is budget neutral, the adjustment has a disproportionate impact on PHPs. Further, this reduction does not, in fact, relate to PHPs costs, and thus works against CMS’s stated goal of ensuring “rates accurately reflect the cost information for providers.” CMS has the flexibility to make adjustments to the payment system to maintain access and ensure adequate payment rates, and the FAH urges CMS to further consider the impact of this large negative adjustment that is unrelated to PHP costs.

DATA COLLECTION PERTAINING TO SERVICES DELIVERED BY OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

The Parameters of the Data Collection Are Much Too Broad

CMS is proposing to engage in data collection regarding the frequency and type of services furnished in off-campus provider-based outpatient departments to improve the accuracy of Medicare payments for services furnished in these settings. Specifically, CMS proposes to create a Healthcare Common Procedure Coding System (“HCPCS”) modifier that would be reported with every code for outpatient hospital services and physicians’ services furnished in an off-campus provider-based department of a hospital.

The FAH understands CMS’s desire to ensure Medicare payment accuracy. However, we believe the data collection effort, as proposed, is much too broad for CMS’s stated purpose and that requiring hospitals to report a HCPCS modifier at the line item level will impose a significant burden on hospitals and physicians. Because of the complexities involved in collecting the data, CMS likely will receive vast amounts of data that will be unclear, inaccurate or irrelevant to the stated purpose of the proposal. Therefore, for the reasons articulated below, we urge CMS to delay the proposal for one year to give CMS the opportunity to work with hospitals and other affected stakeholders to develop a more tailored proposal that can better achieve CMS’s intended goals. This delay also can allow hospitals time to make the necessary system changes and mitigate the reporting burden.
We also are concerned that the proposed data collection and related analysis appear to be focused solely on payment-related information and issues, and may be used as a basis for reducing OPPS payment for some providers. This data collection alone does not capture the cost burdens that are unique to hospitals, is incomplete in terms of developing future payment policy, and should not be used to justify OPPS payment cuts for off-campus provider-based outpatient departments. A more robust analysis is needed to determine hospitals’ costs in providing care, including the cost of furnishing services 24 hours a day, seven days a week, and on an emergency basis, while providing a safety net for those who cannot afford care.

We request that CMS broaden the scope of the analysis to consider hospitals’ unique cost burdens, as well as the improvements in quality of patient care and care coordination that hospitals’ acquisitions help to facilitate. For example, hospital acquisition of physician practices may be for purposes of establishing a demonstration project or an alternative payment model that is necessary to offer more value-based, coordinated care, as contemplated by the Patient Protection and Affordable Care Act (“ACA”). These acquisitions also may be part of a plan to reduce hospital readmissions through better coordination of follow-up outpatient care, along with greater integration and increased capacity to handle patients on an outpatient basis within the hospital’s system. If CMS views the data through the narrow lens of payment-related issues only, this could stifle hospital and physician integration and care coordination efforts, and undermine the Triple Aim goals of the ACA to increase quality, lower costs, and improve access.

Data from All Hospital Off-Campus Provider-Based Departments As Well As Remote Locations Will Undermine CMS’s Collection Effort

The complexities of the proposal begin with the parameters of data collection. The purpose of the data collection, as discussed in the proposed rule, is to understand the resource inputs for services furnished in off-campus, provider-based outpatient departments that formerly were physician office practices prior to acquisition by a hospital. Yet, if all off-campus, provider-based outpatient departments report data, it will be very difficult for CMS to discern which data are from outpatient departments that formerly were physician office practices. Hospitals operate many types of outpatient departments off the main campus of the hospital including departments such as outpatient surgery, physical therapy, outpatient lab, cardiac rehab, wound care clinics, sleep labs, outpatient imaging centers, radiation oncology centers and freestanding emergency departments that never were former physician office practices. Hospitals having a large range of off-campus services will have a significant burden identifying and implementing practices to add the modifier for all of these services. CMS will likely end up with a very large dataset that will provide little value toward the stated purpose.

In addition, it appears that the proposal would include a “remote location” of a hospital as an “off-campus provider-based department.” The proposed rule notes that existing regulations define “campus” as the “physical area immediately adjacent to the provider’s main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main building, and any other areas determined on an individual case basis by the CMS regional office.” Under this definition, a remote campus likely would be
considered “off-campus,” and therefore data would be collected from all remote campuses as well.

Remote locations are not the same as off-campus departments. The remote campus includes full inpatient and outpatient hospital services, in contrast to individual hospital departments. If not clearly excluded from the data collection, data collected from a remote location would not be relevant or comparable to data collected from an off-campus provider-based department as they would include all hospital services within the four walls of the hospital, such as emergency department visits, observation services, and surgical services. These departments are not ones that were formerly a physician office practice, and furnish completely different types of services than a physician office. The ambiguity of whether a remote location is considered off- or on-campus is emblematic of the complexities involved in the data collection proposal, and these complexities threaten to cloud the data collected and render it irrelevant, while undermining CMS’s overall purpose in collecting the data.

Free-Standing Emergency Departments Data Are Not Relevant to the Data Collection

A further complexity is whether free-standing emergency departments (“EDs”) would be considered “off-campus” for purposes of the data collection proposal. These EDs generally furnish very different types of services than are furnished in a physician’s office. They also are required to meet a different accreditation structure, which requires different resource inputs than are required for furnishing services in a physician’s office. Therefore, if data are collected from these EDs, it will further obfuscate the data as well as CMS’s intention to achieve payment accuracy.

Tracking and Discerning Where Many Services Are Furnished Is Difficult and Will Result in Arbitrary Reporting

A final complexity is that CMS proposes to collect data for all services provided in off-campus provider-based departments, including, for example, infusion therapy or chemotherapy services. Data for these types of more specialized services would be very difficult to report, and the result may be data that are inaccurate and problematic to analyze. For example, a blood or urine sample could be collected in an off-campus, provider-based outpatient department, yet the sample may then be sent to the main campus of the hospital for interpretation. This raises the question of where this service is actually furnished, and it will be difficult to make this determination accurately.

CMS also proposes to require physicians (along with hospitals) to report the modifier for services rendered in an off-campus department. Presumably, CMS is attempting to match or otherwise compare the two data sets it will receive. Diagnostic tests that are performed in the off-campus department but interpreted in another location, such as imaging services, will be problematic to define for both physicians and hospitals and could result in different reporting for the professional and technical component. In addition, CMS should keep in mind that not every service will have both a technical component from the off-campus department and a professional component from the physician. Often services furnished in off-campus provider-based departments are performed by hospital staff and hospitals are paid a technical fee for the hospital
staff services, without a corresponding physician professional fee. In these circumstances, CMS will be unable to compare services from both the physician and hospital bills. Because of these complexities, CMS should work with the hospital community, along with other affected stakeholders, to develop a proposal that can operationally result in the collection of accurate data for CMS’s intended purpose.

Alternatively, in consultation with the hospital community and other stakeholders, CMS could consider whether a more targeted, simplified approach yields more accurate data. For example, CMS could consider an approach whereby data are collected for evaluation and management ("E&M") services only. Since these are the most commonly furnished services in physician offices, it may be easier to identify and report these services. This approach also could potentially be more effective in tailoring the proposal to meet CMS’s intended purpose, i.e., understanding the resources used in furnishing services in a former physician office practice prior to acquisition by a hospital. This would also help reduce the burden to both physicians and hospitals and eliminate many of the complications associated with identifying site-of-service for diagnostic services such as laboratories and imaging.

The FAH cautions that an overly broad data collection effort will undermine CMS’s efforts to develop an accurate understanding of the resources involved in furnishing services in these provider-based outpatient departments, while also burdening providers and diverting resources away from patient care. Therefore, we urge CMS to delay the proposal for one year until it can work with hospitals and other affected stakeholders to develop a more tailored plan that collects only the data needed as a basis for Medicare payment accuracy.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES

Removal of Quality Measures from the Hospital OQR Program Measure Set

CMS proposes to apply specific criteria for removal of a “topped out” measure from the OQR Program. The FAH supports the criteria CMS proposes to determine “topped out” measures. CMS also proposes to use the new removal criteria to remove the following three measures from the program with the 2017 payment determination:

- OP-4: Aspirin at Arrival (NQF # 0286);
- OP-6: Timing of Antibiotic Prophylaxis; and
- OP-7: Prophylactic Antibiotic Selection for Surgical Patients (NQF # 0528).

While the FAH supports the removal of topped out measures, the FAH encourages CMS to consider methodologies which might from time to time measure performance on the key measures such as OP-4 and OP-6 measures, which involve an important standard of care that should be maintained.

The FAH is disappointed that CMS is not proposing to permanently remove OP-15 (Use of brain CT in the ED for atraumatic headache) and urges CMS to remove OP-15 from the OQR Program measure set. Public reporting on this measure has been deferred since its adoption, and CMS indicates in the proposed rule that deferral of data collection will continue. While the topic
of the measure is very important and there is evidence that atraumatic brain CTs are likely over used, the measure is not well specified for outpatient department use. At this point, with continual deferral of the implementation of the measure, it should be clear that this measure is not well-suited for the OQR Program and should be refined. While the FAH agrees that this topic area is appropriate for measuring outpatient quality performance, continuing a deferred measure offers no value to consumers and creates uncertainty for hospitals. CMS should remove this measure and seek a better measure on this topic for potential addition to the OQR Program.

In addition, there are several measures in the current outpatient measure setting for which data collection has been suspended or the measures no longer meet NQF criteria, and yet, the measures remain in the program measure set. The FAH strongly recommends that these measures be removed from the program. The 2014 MAP report recommends phase removal of OP-22 (Left Without Being Seen) because it no longer meets NQF endorsement criteria. Last year, the FAH and others urged CMS to remove OQR measures which are not NQF endorsed. While we recognize this is not a statutory requirement, as the FAH has previously stated, NQF endorsement is important for establishing the scientific acceptability of the measure along with feasibility to collect and the usability of the measure to make improvements in care. Again the FAH recommends removal of: OP-9 (Mammography Follow-Up Rates), OP-14 (Simultaneous Use of brain CT and sinus CT), OP-20 (Door to diagnostic evaluation); OP-22 (Left Without Being Seen); and OP-25 (Safe surgery checklist). FAH members welcome the opportunity to work with CMS and others to find topics for future outpatient measure development.

Quality Measures Previously Adopted for the CY 2016 Payment Determination and Subsequent Years

The FAH appreciates that CMS recognizes the problems highlighted by stakeholders as they attempted to report OP-31 (Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery) and proposes for 2016 payment determination to delay data collection and to make OP-31 a voluntarily reported measure in CY 2017. The FAH urges CMS to go further and to withdraw permanently OP-31 beginning with CY 2016. As previously noted in correspondence with CMS, The FAH does not support the proposed continuation of this measure as a voluntary measure beginning with the 2017 payment determination. Consistent with our comments on the 2014 OPPS/ASC proposed rule, the FAH continues to believe that this measure is not appropriate for the HOPD setting and should be removed from the OQR program. Voluntary reporting of a measure with a flawed data collection process as serious as that in this measure does not better inform public choice and should not be used to compare facilities.

The measure was originally specified for use by clinicians and is appropriate in the physician payment setting for which it was endorsed. It was adopted for use in the HOPD and ASC settings prior to it being specified for those settings. Further, the measure was never tested in HOPDs or ASC facilities. It is inappropriate to migrate any measure from the physician’s office to other settings without testing it and specifying it for the setting of intended use and receiving NQF endorsement for the new setting of care. In addition robust testing must be done in the new setting before finalizing a measure for a new setting. As CMS has recognized, hospitals face great difficulties in collecting this measure, which requires the hospital to have information on the patient’s visual function before and after surgery. In addition, CMS now
acknowledges that the measure specifications permit physicians to use several survey instruments to collect the data for determining visual function. Using different surveys leads to inconsistencies in measure data reporting and potentially incomparable data.

The FAH strongly recommends CMS immediately remove OP-31 from the OQR and ASCQR programs. The FAH finds no compelling reason to maintain this measure on a list of differed measures. Limited resources would be better spent on developing or finding more appropriate measures that address care delivered in the outpatient setting. The FAH is glad to work with CMS to identify measure topics which directly reflect the care provided to patients in the outpatient setting.

The FAH is pleased that CMS modified the reporting requirements for the measure OP-27 (Influenza Vaccination Coverage Among Healthcare Personnel) to clarify that hospitals report data for inpatient and outpatient departments as a single number and no longer need to separately report by settings. Further, we note that in the FY 2015 IPPS/LTC final rule published subsequent to the 2015 OPPS/ASC proposed rule, CMS further clarifies that data are to be reported for all patient units included within an NHSN-enrolled facility’s Facility Organization Identification (OrgID) that share the same CCN.

The FAH continues to have concerns about the measures OP-29 (Endoscopy/Poly Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients) and OP-30 (Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps), which were designed as physician measures and were adopted for the OQR Program without having been tested in the hospital outpatient setting. We note that CMS has previously delayed the start of the initial reporting period for these measures from January 1, 2014 to April 1, 2014. We urge that CMS defer these measures until they are fully pilot tested in an outpatient setting.

The FAH urges CMS to remove several current measures from the OQR program based on recommendations from the Measure Applications Partnership. The CMS proposed rule does not address the recommendation of the MAP to remove from the OPPS measure set OP-9 (Mammography Follow-Up Rates), OP-14 (Simultaneous Use of brain CT and sinus CT), OP-15 (Use of brain CT in the ED for atraumatic headache), OP-20 (Door to diagnostic evaluation) OP-22 (Left Without Being Seen); OP-25 (Safe surgery checklist). In addition, several of these measures are not NQF-endorsed either because they no longer meet the criteria for NQF endorsement or NQF endorsement has been removed. The FAH urges CMS to take immediate steps to remove all of these measures from the OQR Program in the final rule.

In the case of OP-15, the data collection was deferred in previous rulemaking and CMS indicates in the proposed rule that deferral of data collection will continue; another clear indication that the measure should be removed from the program. In the case of OP-22, the MAP recommended removal both last year and this year and the measure is no longer NQF endorsed. For measures OP-20 and OP-25, hospitals continue to report difficulty in producing results that are accurate or suitable for public reporting.
Proposed New Quality Measure for CY 2017 Payment Determination and Subsequent Years

The FAH is concerned about the growing list of disconnected measures in the outpatient setting. This disparate list of measures makes it challenging to achieve fundamental change to improve overall patient care. The goal for any quality reporting should be to improve care delivery for patients and encompass information that will help patients better evaluate outpatient quality and help them choose a facility for care that most meets their needs. FAH members are concerned that the proposed measures for CY 2017 do not constitute a set of measures that will be helpful to patient in making personal choices for care, nor does the measure set address issues of greatest importance to hospitals for improving quality in the delivery of the diverse set of services in the outpatient setting?

The FAH does not support the proposed addition of a new claims-based measure, Facility Seven Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (proposed as measure number OP-32) for the 2017 payment determination and later years. The measure has not been endorsed yet by the NQF. The MAP identified a number of issues that would be addressed during NQF review, including reliability and validity testing and the attribution of colonoscopies to HOPDs in light of the IPPS 3-day window policy. CMS offered brief remarks on these issues in the proposed rule, however, those remarks are not a substitute for the comprehensive review and multi-stakeholder input that occurs during the NQF measure endorsement process.

The FAH reviewed the measure as it is under endorsement review by NQF, the FAH is troubled by the reported reliability data and the lack of measure exclusions for unrelated hospital admissions. The NQF measure submission for OP-32 shows the developer assessed reliability using the “test-retest” method, which the degree to which repeated measurements of the same entity agree with each other. A reliable measure would be expected to have a high degree of agreement. In the case of proposed OP-32, the measure developer indicates with two years of data that the measure is “fairly” reliable. On a scale of zero to one, the score for this measure was 0.335 using two years’ worth of data. This score is not a strong enough indication of reliability to move the measure into public reporting. The FAH is concerned that with such low reliability, patients and others could easily draw incorrect conclusions about the meaning of the measure score.

It is unclear if the measure would have greater reliability if it used more than two year’s work of data. For instance, the readmission measures used in the IQR program use three years’ worth of data. The FAH encourages the measure developer to explore using additional data to see if reliability improves.

The FAH also encourages the measure developer and CMS to expand the number of unrelated colonoscopy procedures. We appreciate that the measure includes a mechanism for excluding hospital visits for certain “planned” procedures, and we would encourage the developer to expand that list to also include bone fractures and behavioral health disorders. The usability of the measure is compromised if additional unplanned admissions unrelated to colonoscopy are not excluded.
In addition to obtaining NQF endorsement, and should CMS go forward with OP-32, the FAH strongly recommends that prior to adoption of this measure or any claims-based measure, CMS conduct a dry-run calculation under which hospitals can review the results of CMS calculation on the measure using claims from a similar time period (in this case a 12-month period or a more if the measurement period is expanded during the NQF review process). Such a trial period would help identify issues with the measure specifications and aid in hospital understanding of the measure. This should occur prior to adoption of any claims-based measure.

As the FAH has stated in a number of previous comment letters to CMS, measure results for claims-based outcomes measures should be made available more often than once per year. Hospitals need more timely data in order to use the measure results to inform changes in care processes and make improvement in quality.

Finally, if CMS moves forward with this measure, the FAH strongly opposes the proposed data collection timeline for this measure, which would begin on July 1, 2014, prior to the issuance of a CY 2015 OPPS/ASC final rule. It is inappropriate for hospital performance on this measure to be assessed and publicly reported for a time period prior to the measure’s adoption for the OQR Program. In this case, the proposed data collection period is 12 months, almost half of which would be prior to the issuance of the final rule.

Possible Hospital OQR Program Measure Topics for Future Consideration (PHP)

CMS is proposing to add a new quality measure of the PHP care to the OQR Program. The FAH believes it is premature to add new PHP quality measures at this time and strongly recommends that CMS develop a plan for studying what topics are the most important to be addressed from a health care provider and patient perspective in PHP care. CMS should actively engage stakeholders to determine which issues of care they believe would best address their concerns about quality in the PHP setting. In addition, as the FAH has commented in the past on the development of any new quality element, the purpose of the quality measurement must be clear. Any measures to be used in the program must first be endorsed by the NQF for that setting of care and reviewed by the MAP. The NQF review ensures the importance of the measure, the scientific validity and reliability of the measure and the feasibility of collecting the data and the usability of the data produced by the measure.

In particular, CMS seeks public comment on the three PHP measures: 30-Day Readmission, Group Therapy, and No Individual Therapy. These three measures are included in the PHP Program for Evaluating Payment Patterns Electronic Reports (PEPPER) developed under the Comprehensive Error Rate Testing Program. CMS also invites public comment on other potential PHP measures and on the utility of including PHP measures in the OQR Program given the decline in PHP utilization. The FAH recommends that CMS look at the overall issues related to the Partial Hospitalization benefit in a more comprehensive way to ensure that our nation’s mental health system with shrinking resources and access to care is able to provide the right care in the right setting. Imposing a payment reduction for PHP programs that might fail to meet OQR requirements would further destabilize the PHP payment rate and threaten access to necessary psychiatric care. The FAH is willing to work with CMS and others to identify and develop the most appropriate measures for PHP quality reporting.
We know from the implementation of the Inpatient Psychiatric Facility quality program that careful thought must be given to the measure selection, methodology for data collection and data attribution. While CMS proposed to the MAP three measures for PHP quality evaluation, the MAP did not support these measures in its report to the Secretary in February 2014 largely because the measures were not NQF endorsed.

The MAP also indicated that the therapy measures are backed by limited evidence of the relative value of individual versus group therapy, and that the readmission measure is poorly defined. CMS should not add these measures with a PHP focus to the OQR Program. The measures need to be properly specified for and tested in partial hospitalization programs in the HOPD setting, endorsed by the NQF, and reviewed again by the MAP.

In addition, the FAH believes that any new methodology for submitting measures should also be tested prior to implementation. For instance, experience during program year CY 2013 indicates the need for stronger support of the infrastructure for reporting Hospital Based Inpatient Psychiatric Services (HBIPS) measures. Before adding additional mental health measures to the OQR program, the infrastructure must be fully supported.

In addition to the PHP measures, CMS indicates it is considering other measures specific to behavioral health in the outpatient setting. Measures under consideration include measures of depression and alcohol abuse “because of the prevalence of depression and alcohol abuse and their impact on the Medicare population,” according to the proposed rule. Before additional measures of behavioral health are added to the OQR, a great deal of additional work needs to be undertaken to identify, define, test and educate providers on the use of behavioral health measures that can ultimately improve patient care in the hospital outpatient setting.

Requirements for Reporting of Hospital OQR Program Data for the 2017 Payment Determination and Subsequent Years

The FAH believes that data validation is a critical element of effective quality reporting programs, and supports the proposed three changes to the data validation procedures for OQR Program measures. These changes would: 1) modify when a hospital is eligible for selection to the validation sample to include those hospitals that have submitted at least one case to the Hospital OQR Program Clinical Data Warehouse during the quarter containing the most recently available data, determined by when the sample is drawn; 2) give hospitals the option to either submit paper copies of patient charts or securely transmit electronic versions of medical information for validation, a procedure already adopted for the IQR Program, and 3) make a technical change to clarify that when the hospital identify to the designated CMS contractor the medical record staff responsible for record submission, that the contractor may be an entity other than a Quality Improvement Organization.

The FAH supports the extension of the extraordinary circumstances provisions for CY 2017. The ability to apply for an extension for all applicable quality reporting programs at one time is a welcome change. CMS proposes to retain the existing OQR Program procedural requirements for the current four month data submission and reporting. However, as the FAH understands the proposal, CMS proposes to eliminate the separate date review process period
currently in place. The FAH does not support this proposal. The data submission and review process does not substitute for a separate review and corrections period. It is important for hospitals to be able to have the opportunity to review data in aggregate and submit corrections as necessary. To include the final review process during the data submission period essentially shortens the period of time hospitals have to submit data. The FAH recommends a 30 day review period immediately following the data submission period. The FAH believes this will help CMS facilitate timely data process while also allowing hospitals the full amount of allowed time to submit measure data.

The FAH encourages CMS to ensure that contractors in the new Quality Improvement Networks (QINs) are adequately staffed to assist hospitals as quarterly reporting deadlines approach. Hospitals operate 24 hours per day, 365 days per year. Hospitals need to be able to reach technical support personnel outside normal business hours, particularly as deadlines for reporting approach. The quality improvement work of hospitals is conducted regardless of the time of day or day of the week.

**REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM**

The FAH believes that to the extent possible, quality measures should be aligned across sites of care, and in that light we appreciate that CMS is making proposals to remove and add measures to the ASC Quality Reporting Program in parallel with proposals for the OQR Program. However, for the reasons discussed earlier we do not support the addition of the Facility Seven Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy measure until it is NQF endorsed, reliability is improved and a proper/complete dry run has been provided to offer ASCs the opportunity to identify issues with the measure. Therefore, CMS should not finalize the addition of this measure at this time. Further, the proposed timeline inappropriately would begin July 1, 2014, which is several months prior to the point at which the measure’s adoption would be finalized in the OPPS/ASC final rule.

Again, consistent with the OQR Program, while we support the decision to not require reporting of the measure *Cataracts – Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery* for 2016 payment, we strongly urge CMS to permanently remove this measure from the ASCQR, for all the same reasons the FAH opposes the measure’s inclusion in the OQR program. The FAH does not support the proposed continuation of this measure as a voluntary measure beginning with the 2017 payment determination.

The FAH continues to have concerns about the absence of a data validation process for the ASCQR Program involving independent review of medical records. The value of public reporting depends on the accuracy and integrity of the data that is submitted. At a minimum, where the same measures are adopted for both the ASCQR and the OQR programs, data validation requirements should also be the same in both settings. It is inappropriate to suggest that consumers can compare performance on similar or identical measures between the ASC and OPD settings if data are validated in the OPD setting and not in the ASC setting.
CMS proposes a measure removal policy for the ASCQR. This policy for removal is the same as the policy in the IQR program, which permits immediate removal of a measure from the program if it is determined that continued reporting would lead to patient harm. This removal could occur without formal rulemaking. The FAH supports this policy and appreciates the consistency in these processes across programs.

**CMS-IDENTIFIED OVERPAYMENTS ASSOCIATED WITH PAYMENT DATA SUBMITTED BY MEDICARE ADVANTAGE (“MA”) ORGANIZATIONS AND MEDICARE PART D SPONSORS**

CMS proposes to specify in regulations the procedural mechanism used by CMS to recoup overpayments associated with errors identified by CMS in payment data submitted by MA organizations and Part D sponsors in circumstances where the organization has not corrected the erroneous data. As CMS moves forward in implementing this process through regulations, the FAH urges CMS to do so with certain considerations in mind.

CMS proposes to request corrections to erroneous payment data using a six-year look back period, beginning with contract year in 2010. CMS should recognize that a six-year look-back could affect many distributed risk arrangements between plans and providers that cross multiple years and have already been reconciled. Reopening these arrangements would be unwieldy, and any retroactive, unanticipated recoupment for already executed, prior year arrangements would be extremely disruptive for these risk-based contracts. Therefore, any look back period should only apply going forward so that these circumstances can properly be addressed in future contracts. Further, the look back period should be implemented on a “stair-step” phased-in basis, beginning with a one-year look back and each year adding an additional year to the look back period until 2020 when a six-year look back could be applied.

Further, in cases in which an MA organization or Part D sponsor appeals CMS’s decision, the FAH urges CMS to ensure any associated provider record requests are limited to the specific instance of erroneous data under dispute. As the FAH has previously commented, we believe that in certain instances MA organizations leverage RADV audits or other CMS-initiated data requests to obtain hospital inpatient, hospital outpatient, and physician/practitioner provider records above and beyond those needed for the specific issue under consideration. Therefore, the FAH suggests that the MA organization requesting medical records be required to provide documentation on the scope of the erroneous data dispute identified by CMS and to limit the data request to the specific data issue identified. This will ensure that the MA organization and CMS have the necessary information, while at the same time limiting the administrative burden on providers.

**PROPOSED REVISION OF THE REQUIREMENTS FOR PHYSICIAN CERTIFICATION OF HOSPITAL INPATIENT SERVICES OTHER THAN PSYCHIATRIC INPATIENT SERVICES**

CMS proposes to apply a certification requirement for inpatient hospital services only for cases (other than inpatient psychiatric facility services) that are 20 inpatient days or more, or are
outlier cases. Under the certification, a physician would certify or recertify the reasons for the continued hospitalization of the patient for medical treatment or study, or for special or unusual services for outlier cases, along with the estimated time the patient will need to remain in the hospital and plans for post-hospital care, if appropriate. This requirement will no longer apply to cases that are less than 20 days.

The FAH applauds CMS for removing the certification requirement for stays less than 20 days. We agree with CMS that requiring the certification does not outweigh the associated administrative requirements placed on hospitals.

In removing the certification requirement for inpatient stays less than 20 days, the proposed regulatory text understandably eliminates the requirement that a certification be signed prior to discharge. With regard to a physician’s admission order, the proposed regulatory text maintains that a physician’s admission order must be present, but it does not require that a physician’s admission order be authenticated or countersigned before discharge as the current regulatory text requires for certifications.

The FAH strongly believes that CMS should affirm in the final rule that a physician’s verbal admission order need not be authenticated prior to discharge, but only within a reasonable time. CMS should affirm the same for admission orders by emergency department physicians that require countersignature by a physician with admitting privileges. While hospitals endeavor (and succeed in most cases) to accomplish these authentications prior to discharge, it does not happen in every case, and CMS’s policy should not serve as “gotcha” in cases where authentications do not occur prior to discharge, but occur within a reasonable period of time.

Notably, the approach we ask CMS to affirm is consistent with CMS’s broader policy regarding authentication of verbal orders for other types of services, which requires authentication within a reasonable time period. While we think CMS’s policy regarding authentication of physician admission orders would now seem clear, a January 30, 2014 CMS bulletin addressing Hospital Inpatient Order and Certification creates ambiguity by applying the “prior to discharge” timing requirement for authentications to both the certification requirement (now being eliminated) and a physician’s inpatient order.

The burden of obtaining authentication before discharge is equally challenging and burdensome for both certifications and physician admission orders. It involves logistical challenges, such as those associated with electronic health record functionality, which may make it difficult to enter the physician authentication prior to discharge. This is confusing and frustrating to patients because it may result in delayed discharge or a stay that is reimbursed under Part B. It is also especially difficult in verbal order situations. A verbal order for inpatient admission is directly communicated by medical staff, documented in the medical record when it is received, and identifies the qualified admitting practitioner, which is consistent with governing general requirements for verbal orders. It also initiates the medical care and start of the inpatient admission. Therefore, the requirement that the ordering practitioner countersign a verbal order, prior to discharge, is arbitrary, unnecessary, and detracts from patient care and may affect patient status in particular cases.
Further, the timing requirement is also especially problematic when an ordering physician must countersign the order, prior to discharge, when a medical resident, non-physician practitioner, or emergency department or other physician without admitting privileges, acts as a proxy for the ordering practitioner. The same feasibility issues that arise with authenticating verbal orders prior to discharge also apply to this requirement, and thus the “prior to discharge” requirement should be eliminated.

We appreciate and support CMS’s proposal to scale back the certification requirement, and believe CMS also should affirm that an inpatient admission order need not be authenticated prior to discharge, which will help reduce hospitals’ administrative burden related to a form over substance technical requirement.

Additionally, we urge CMS to maintain physician order and certification requirements as CMS Program Manual Instructions, not as formal regulatory requirements.

Including admission order and certification as formal regulatory requirements limits Medicare contractor and ALJ discretion when reviewing appeals of Part A denials. Previously, if a Part A denial included inadvertent, technical non-compliance with order or certification requirements set forth in CMS Manual Instructions, Medicare contractors and ALJs had discretion to determine “substantial compliance.” Issuing order and certification requirements as regulations puts form over substance, limits the contractor and ALJ discretion, and results in claims denials for purely technical reasons, despite that the medical services were medically necessary and actually furnished to patients.

**DRUGS AND BIOLOGICALS**

New Level II HCPCS Codes Implemented in July 2014 (79 FR 40975)

CMS introduced new Level II HCPCS codes July 1, 2014 eligible for comment during the CY 2015 OPPS/ASC proposed rule comment period. HCPCS code C9134 was created with the description “per 10 i.u.”; however, other coagulation factors are currently represented by the following HCPCS codes with dose descriptions of “per i.u.”: J7180, Injection, Factor xiii (antihemophilic factor, human), 1 i.u., J7185, factor viii (antihemophilic factor, recombinant) (xyntha), per i.u.; J7192, Factor viii (antihemophilic factor, recombinant) per i.u., not otherwise specified; and J7195, Factor ix (antihemophilic factor, recombinant) per i.u.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C9134</td>
<td>Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 i.u.</td>
<td>G</td>
<td>1481</td>
<td>14.10</td>
</tr>
</tbody>
</table>
The FAH recommends that the description be “PER IU” rather than “PER 10 i.u.” as introduced. This product is a single use vial which is lot-specific with each lot varying from 2000 to 3125 IU. The establishment of the HCPCS code per each IU is consistent with other coagulation factors as noted above and will result in more precise payment for the actual dose administered to the patient.

In addition, we note that the proposed payment rate is not aligned with the manufacturer reported WAC pricing (dated April 2014) of $13.30 per IU. The proposed CY 2015 payment rate is $14.10 per 10 IU, which does not meet the ASP + 6 percent payment rate. The proposed payment rate of $14.10 would be consistent with the manufacturer reported WAC pricing if the description was updated to PER IU.

Proposed Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages (79 FR 41001)

CMS recognizes a single packaging determination, rather than individual HCPCS codes reporting different dosages, for the same covered Part B drugs or biologicals for OPPS payment purposes to eliminate payment incentives for hospitals to report certain HCPCS codes for drugs and to allow hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. The FAH recommends inclusion of additional HCPCS codes to which this CY 2015 Drug-Specific Packaging Determination Methodology would apply. The following products contain the same drug with multiple HCPCS codes describing different dosages and are not listed in the CY 2015 Proposed HCPCS code list (Table 41 – 79 FR 41001).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>J7060</td>
<td>5% dextrose/water (500 ml = 1 unit)</td>
<td>N</td>
</tr>
<tr>
<td>J7070</td>
<td>Infusion, d5w, 1000cc</td>
<td>N</td>
</tr>
<tr>
<td>J1950</td>
<td>Injection, leuprolide acetate (for depot suspension), per 3.75 mg</td>
<td>K</td>
</tr>
<tr>
<td>J9217</td>
<td>Leuprolide acetate (for depot suspension), 7.5 mg</td>
<td>K</td>
</tr>
</tbody>
</table>

The “CY 2015 Proposed HCPCS Codes to Which the Drug-Specific Packaging Determination Methodology Would Apply” includes normal saline infusions with various dosage descriptions (250 cc, 500 mL, 1000 cc). HCPCS codes for dextrose 5%/water (D5W) solutions are available in different dosages; however, they are not currently included within the drug-specific packaging determination methodology. The FAH recommends the addition of HCPCS codes J7060, 5% dextrose/water (500mL = 1 unit) and J7070, Infusion, d5w, 1000cc to be added for single packaging determination.

Hospitals are challenged with distinguishing the appropriate HCPCS code to report leuprolide acetate products for depot suspension. These products are FDA-approved for a variety of indications, including palliative prostate cancer and endometriosis, with various dosing
schedules as per CMS-approved compendia. CMS payment rates vary from $760.03 for HCPCS code J1950 (per 3.75mg) to $206.78 for HCPCS code J9217 (per 7.5mg). According to the July 2014 ASP NDC-HCPCS Crosswalk for Medicare Part B Drugs, J1950 is used to report Lupron Depot 3.75mg and 11.25mg and Lupron Depot-Ped 11.25mg and 30mg, while J9217 is used to report Eligard 7.5 mg, 22.5 mg, 30 mg, and 45 mg, Lupron Depot 7.5mg, 22.5mg, 30mg and 45mg, and Lupron Depot-Ped 7.5mg and 15mg.

The FAH recommends the addition of these codes to the single packaging determination methodology to eliminate payment incentives for hospitals to report certain HCPCS codes for drugs and to allow flexibility and clarification in choosing to report all HCPCS codes or only the lowest dosage HCPCS code, which is “per 3.75 mg” for this example: HCPCS codes J1950, Injection, leuprolide acetate (for depot suspension), per 3.75 mg and J9217, Leuprolide acetate (for depot suspension), 7.5 mg.

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil at 202-624-1529.

Sincerely,