June 16, 2015

Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W., Room 445-G  
Washington, DC 20201

SUBJECT: CMS-1632-P. Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Records Incentive Program; Proposed Rule, April 30, 2015

Dear Administrator Slavitt:

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 comment to the Centers for Medicare & Medicaid Services (“CMS”) about the referenced Notice of Proposed Rulemaking on the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Records Incentive Program; Proposed Rule, April 30, 2015 (“Proposed Rule”).
EXECUTIVE SUMMARY

Disproportionate Share Hospital Payment

The FAH again expresses its appreciation for the way in which CMS initially engaged the hospital industry regarding the system to calculate and ensure payment of Factor Three uncompensated care pool allocations, and strongly supports CMS’s proposal to retain that system for FY 2016. We are concerned, however, that CMS may be understating the Medicaid expansion and the amount of DSH that would be paid in FY 2016 but for ACA section 3133, as it did for FY 2014, which significantly understates the DSH pool that is used to calculate Factor One and ultimately impacts the calculation of the Additional DSH funding pool in Factor Two. We strongly urge the agency to study the cost report analyses included in our comments, and to reexamine its assumptions regarding hospital utilization by the newly enrolled Medicaid beneficiaries. It defies logic that in the first year of the ACA Medicaid expansion, with a previously unmet, pent up need for care in the low income population that Medicaid expansion would lead to fewer hospital services.

In addition, the FAH is concerned that a decision in favor of King, in the Supreme Court case King v. Burwell will lead to an increase in the uninsured population that is not reflected in CBO’s current coverage estimate for FY 2016, which CMS uses to reduce the UCC DSH payment pool. Therefore, should the Supreme Court rule for King, the FAH urges the Secretary to take appropriate action such as using her authority to adjust the estimate of the FY 2016 uninsured population in the final rule, or issuing an interim final rule and adjusting the FY 2016 coverage estimate following a revised estimate from CBO.

Simplified Cost Allocation

The FAH strongly opposes CMS’s proposal to eliminate simplified cost allocation methods for hospitals. The proposal is based on clearly erroneous assumptions. CMS concludes that only 23 PPS hospitals use this methodology when, in fact, nearly 2000 hospitals do, as detailed in our comments below. The elimination of the simplified cost allocation option would create significant and unnecessary administrative burdens on hospitals with little to no impact on hospital reimbursement. Instead, CMS should explore with industry additional ways in which we can work together to simplify the cost report itself, not add to the burden by eliminating one important method so many hospitals now use to ease the burden.

If CMS is concerned with the underlying data it uses to weight imaging-related services in related MS-DRGs, there are better alternatives than disrupting the cost reporting practices of a very large number of hospitals that do not use “dollar value.” With a significant portion of the hospitals apparently using dollar value to allocate major moveable equipment, CMS could use that data as a reasonable and accurate proxy to estimate what the impact would be if all hospitals used dollar value. If such an estimate results in a material difference, CMS could then adjust all of the relative MS-DRG and APC weights accordingly.
Short Inpatient Hospital Stays

The Proposed Rule does not propose any changes to the two-midnight policy. Instead, noting ongoing concerns of stakeholders related to the two-midnight rule, the Proposed Rule indicates that hospitals should look to the upcoming proposed rule for the Medicare hospital outpatient prospective payment system (“OPPS”) for additional discussion. We look forward to reviewing the OPPS rule for this purpose. We are hopeful that the upcoming OPPS discussion on the two-midnight policy will reinstitute greater weight to a physician’s clinical judgment in determining hospital patient status issues and recognize the clinical legitimacy of one-day hospital stays. Our comments describe policies CMS should put in place to help ensure that outcome.

In addition, based on the analysis detailed in our letter that clearly refutes OACT’s projection that the two midnight rule would generate 40,000 more inpatient admissions, the FAH strongly urges CMS to restore the 0.2 percent reduction for FY 2016 and to compensate hospitals for the payment losses sustained as a result of the application of the 0.2 percent reduction in FY 2014 and FY2015.

Bundled Payments for Care Improvement (BCPI) initiative

The challenges of transitioning from fee-for-service to value-based payment are numerous and complex, and will require time, experience, and significant investment by both the public and private sectors in order to succeed. As CMS considers whether and how to expand the BPCI initiative, it is important that CMS leadership recognizes the clear limits of its authority to mandate participation in an expansion and the degree to which the health care delivery system is prepared for such an expansion and ways in which providers can best support the goals of reduced costs, higher quality care, and improved population health.

Any near-term expansion of the BPCI initiative should preserve the ability of providers to be flexible in choosing the types of episodes, duration, and degree of risk; in addition, CMS could consider expanding the options available to providers, such as a prospective Model 3 episode, to continue the process of testing and evaluating different payment models. However, regulatory differences across post-acute care (PAC) providers that impact the cost of care in different settings—such as staffing ratios, conditions of participation, and patient clinical criteria—could prevent the provision of appropriate, necessary care within episodes and should be eligible for waivers. CMS should also revise the precedence rules that determine to which episode a beneficiary is attributed (e.g., to a physician, hospital, or post-acute care provider) in order to promote a level playing field for hospitals to participate in the BPCI initiative.

In addition, CMS should consider making adjustments to the methodology used to set payments under the BPCI initiative in order to improve risk adjustment, take into account regional differences in beneficiary health status, and create an environment with more predictability as providers gain experience with delivering care under episode-based payments. The role of third party organizations—particularly as risk-bearing awardee conveners—in the BPCI initiative must be addressed by CMS as well in order to protect both patients and
providers, as these organizations have the potential to influence how acute care and PAC are paid and delivered in ways that were not predicted when the initiative first launched.

**Long Term Care Hospital Payment**

While we are pleased that the criteria CMS has proposed to qualify an LTCH discharge for payment under the LTCH PPS follows Congressional intent, we are troubled by the requirements CMS would impose to establish that the LTCH admission was “immediately preceded” by a discharge from a subsection (d) hospital. CMS should determine compliance with the immediately preceded criterion based on information contained in the LTCH claim, not whether the discharging subsection (d) hospital included Patient Discharge Status Code 63 or 91 on its claim. An analysis of hospital claim data demonstrates the coding challenges acute hospitals experience with these discharge codes, based in part on confusing guidance issued by CMS.

In addition, we urge CMS not to finalize proposals to apply to site neutral cases the interrupted stay payment policy as well as the 25% rule. The FAH also recommends that with respect to MS-LTCH-DRG relative weights CMS construct two sets of weights, one of which would be based on the full set of cases in the MedPAR file and would apply to discharges that occur in cost report periods that begin before October 1, 2015; and the second of which would be based on a subset of MedPAR cases and would apply to discharges in cost report periods that begin on or after October 1, 2015. Finally, the FAH recommends that CMS establish two outlier target amounts, or pools - one for cases paid under the LTCH PPS, with an 8% target amount and a $13,783 fixed loss threshold, and the other for site neutral cases, with a target amount and fixed loss threshold identical to the FY 2016 IPPS rule, as CMS has proposed.

**Mandatory eCQM Reporting**

The FAH strongly opposes the proposed mandatory reporting of electronic Clinical Quality Measures (“eCQMs”) in the IQR program or any other quality or payment program, such as Meaningful Use (“MU”) or Hospital Value-Based Purchasing (HVBp) at this time. The current eCQMs are not specified consistently across Vendors, and the data they generate is not comparable to the chart-abstracted data on the same measures. CMS should work with the Office of the National Coordinator (“ONC”) to ensure that eCQMs are improved to be reliable and valid and supported by all vendors prior to expansion of their use. The FAH supports efforts to move toward electronic health record (“EHR”) reporting in the future, and to align quality reporting under the IQR with the Medicare EHR Incentive Payment.

**Pneumonia Measures Expansion**

The FAH opposes the CMS proposed expansion of the patient cohort for the pneumonia readmissions and mortality measures for use in the Inpatient Quality Reporting (“IQR”) and Hospital Readmissions Reduction Programs (“HRRP”). The proposed expansion would add patients with a principal diagnosis of aspirational pneumonia and also those with a discharge diagnosis of sepsis or respiratory failure who had a secondary diagnosis of pneumonia present on admission. The revised measures should be tested and evaluated as part of the trial period for
socio-demographic assessment. The expanded measures also should be resubmitted to the NQF for endorsement and to the Measure Applications Partnership (“MAP”) for reconsideration and recommendation. Until the pneumonia readmission measures are endorsed and fully specified, the FAH cannot support the measures.

IQR Measure Expansion

CMS proposes expanding the Hospital Inpatient Quality Reporting Program (“IQR”) beginning with the FY 2018 payment determination. The FAH is disappointed that none of the proposed measures has been endorsed by the NQF, and for that reason alone the FAH cannot support addition of these measures. The FAH historically has opposed the addition of structural measures in the IQR program because “check-the-box” measures generally do little to provide actionable information for hospitals to improve patient care. Should CMS choose to proceed with the proposed measure, the FAH strongly encourages CMS to specify which tool(s) should be used and CMS should consider adopting this survey measure as a one-time or periodic survey rather than a required annual survey reporting requirement.

LTCH IMPACT Implementation and Quality Reporting

The FAH encourages CMS to use only quality measures that are endorsed by NQF and recommended by the MAP for both IMPACT implementation and in the ongoing LTCH QRP. The FAH strongly recommends that CMS modify the CARE Data Set to ensure consistent and necessary data that will appropriately and accurately populate the necessary quality measures. As we have recommended for other quality payment programs, the FAH encourages CMS to adjust the readmission measure to include socio-demographic risk adjustment. The FAH supports the proposed preview period for reporting of the LTCH QRP prior to its being posted on a public website. The FAH strongly encourages CMS to permit LTCHs to correct their data during the preview process. The LTCH quality reporting display should be included on a website separate from Hospital Compare. It would be confusing to have multiple types of providers included in the same website.

MS-DRG Documentation and Coding

II.D. Proposed FY 2016 MS-DRG Documentation and Coding Adjustment

The American Taxpayer Relief Act of 2012 (ATRA) requires CMS to recover $11 billion in alleged overpayments made in FYs 2010, 2011 and 2012 due to the effect of documentation and coding changes and CMS delay in implementing prospective rate adjustments to remove the coding-related case-mix increases. ATRA specifies the amount of the reduction, $11 billion, and requires that it be recovered over FYs 2014, 2015, 2016, and 2017.

In the FY 2014 and FY 2015 final rules, CMS reduced payments by 0.8 percent each year to fulfill part of that mandate, noting that it intended to phase-in the reductions over time, a policy encouraged and strongly supported by the FAH. In the FY 2016 proposed rule, CMS again proposes to reduce payments by an additional 0.8 percent. While the FAH disagrees with the
determination that $11 billion in overpayments occurred in the referenced fiscal years, we recognize that ATRA does not give CMS discretion on the amount to be recovered. The FAH does appreciate, however, and strongly supports CMS applying the discretion it does have to phase-in the reductions as proposed and mitigate, to the extent possible, the impact of the ATRA payment cut on hospitals.

**Bundled Payments for Care Improvement Initiative**

**II.H.4 Solicitation of Public Comments on Expanding BPCI Initiative**

**Summary of Comments**

The challenges of transitioning from fee-for-service to value-based payment are numerous and complex, and will require time, experience, and significant investment by both the public and private sectors in order to succeed. As CMS considers whether and how to expand the BPCI initiative, it is important that CMS leadership recognizes the clear limits of its authority to mandate participation in an expansion and the degree to which the health care delivery system is prepared for such an expansion and ways in which providers can best support the goals of reduced costs, higher quality care, and improved population health.

Any near-term expansion of the BPCI initiative should preserve the ability of providers to be flexible in choosing the types of episodes, duration, and degree of risk; in addition, CMS could consider expanding the options available to providers, such as a prospective Model 3 episode, to continue the process of testing and evaluating different payment models. However, regulatory differences across post-acute care (PAC) providers that impact the cost of care in different settings—such as staffing ratios, conditions of participation, and patient clinical criteria—could prevent the provision of appropriate, necessary care within episodes and should be eligible for waivers. CMS should also clarify the precedence rules that determine to which episode a beneficiary is attributed (e.g., to a physician, hospital, or post-acute care provider) in order to promote fair competition between participants in the BPCI initiative.

In addition, CMS should consider making adjustments to the methodology used to set payments under the BPCI initiative in order to improve risk adjustment, take into account regional differences in beneficiary health status, and create an environment with more predictability as providers gain experience with delivering care under episode-based payments. The role of third party organizations—particularly as risk-bearing awardee conveners—in the BPCI initiative must be addressed by CMS as well in order to protect both patients and providers, as these organizations have the potential to influence how acute care and PAC are paid and delivered in ways that were not predicted when the initiative first launched.

**Breadth and Scope of Expansion**

**Key Questions:** Should expansion of the BPCI initiative be voluntary or mandatory? Should CMS focus on one or more of the four models being tested in the BPCI initiative? Should expansion target specific regions of the country?
**Scope of Authority**

It is unclear just how far CMS may be envisioning a potential expansion of the BPCI initiative, or for that matter any other current or future initiatives under the oversight of the Center for Medicare and Medicaid Innovation (“CMMI”). The Proposed Rule’s question of whether BPCI models should be expanded with voluntary participation or whether it would be more effective if participation were required within certain models, episodes or regions raises cause for concern.

CMMI appears to be implementing the BPCI initiative through CMMI’s general program authority. The CMMI’s general authority is to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing quality of care. (SSA §1115A(a)(1).) CMMI has the authority to waive certain Medicare program requirements “as may be necessary solely for the purposes of . . . testing [CMMI] models.” (SSA §1115A(d)(1).) These waivers apply to Titles XVIII and XI of the Social Security Act, among other authorities, and solely to the testing phase of the CMMI authority.

The law further directs CMS to evaluate CMMI models and, if appropriate, allows CMS to expand “the scope and duration” of an existing model to a “Phase II,” provided certain requirements are met. (SSA §1115A(c).) Given how the law is drafted, Congress did not provide for the waivers available under the testing phase (i.e., Phase I) to continue being available under the expansion phase (i.e., Phase II). If Congress had intended otherwise, it would have explicitly provided for Phase II waivers.

The law also requires CMS to report periodically to Congress on CMMI models and make proposals for legislative action on models as it deems appropriate. (SSA §1115A(g).) This means that any permanent or mandatory changes to Medicare payment systems must be enacted by Congress. This is not surprising, as Congress has always taken legislative action to make changes to Medicare payment systems, while allowing CMS to test new models. If any such authority was being ceded to CMMI in this regard, Congress would have been much more specific in stating so. We find nothing in the law or legislative history that supports such a delegation of authority, and in fact the limited legislative history on this provision indicates the exact opposite.

We believe the statutory construct is clear: CMS is to test innovative models and can grant certain waivers to do so, to expand effective models for broader testing as appropriate without the protection of waivers, and to make recommendations to Congress for permanent or mandatory changes to the Medicare program for deserving models after rigorous testing.

In our view, CMS’s authority does not extend to taking unilateral administrative action to make a CMMI model permanent and/or mandatory, either at a regional or national level. Mandating participation in a particular program is just not envisioned in what the law allows to expand the “scope and duration” of CMMI models in a Phase II. Given the start-up costs and commitment to infrastructure necessary to participate in the BPCI initiative, it is hard to fathom that Congress intended for CMS to be able to mandate this of providers, as it could raise concerns about unfunded mandates among other concerns.
Moreover, given there is no waiver authority associated with Phase II and CMS cannot under any scenario waive state laws, we believe it is very unlikely that Congress would have intended to give CMS model expansion authority to mandate a program for providers that could force them to run afoul of both federal and state fraud and abuse laws.

We urge CMS to keep participation in BPCI and all other CMMI test and expansion models voluntary at all times, as Congress intended, and as has been the case historically with all Medicare program pilot and demonstration projects. Again, any Congressional delegation of authority to change Medicare payment systems would have been more expressly granted, and CMS should not infer such intent in current law.

Policy Considerations

In deciding whether or not to expand the BPCI initiative beyond Round 2 and how an expansion could take shape, there are a broad range of issues that CMS must consider. Primarily, in order for the BPCI initiative to be transformational in how care is delivered, both financial/business and clinical models will need to be substantially revised and recalibrated by CMS as well as providers participating in the BPCI initiative. The transition from fee-for-service reimbursement of acute and post-acute care under “silied” prospective payment systems to episode-based payments in the Medicare program would represent a substantial change in the way the health care industry is structured to deliver patient care and how CMS payments are structured. Such a change would require time for adjustment and extensive shifts in organizational culture and business models—both within hospitals as well as among other providers and related social institutions and support networks—across the full continuum of care.

For this reason, any further expansion of the BPCI initiative, both in terms of the providers participating and the models/episodes selected, must be voluntary and pursued cautiously until we know more about how the BPCI initiative leads participants to change business models, patient care delivery, provider financial risk, and the organizational structures required to accept and manage these risks and challenges. In order to take advantage of the opportunities presented by payment bundling, providers will need to possess (or quickly develop) numerous organizational capabilities, including: an entity responsible for managing the payments and financial risk; administrative, clinical, and data analytic infrastructure to redesign clinical and administrative processes; affiliations with physicians; and strong networks with other acute and post-acute care (“PAC”) providers.\(^1\) Implementation of any payment bundling system clearly requires significant investment in not only human resources, but also physical infrastructure and capital.

For example, providers will need to identify, implement, and evaluate a range of clinical interventions specific to each type of episode to determine which are effective in improving patient outcomes and efficient to deliver under a bundled payment system. These clinical interventions will require investment in new staff, such as nurse specialists and care transitions coaches, as well as health information technology and other administrative tools. Such

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investment will ultimately be necessary to increase data collection and information-sharing across newly formed networks of providers that currently do not have the infrastructure to transmit the level of detailed clinical information necessary to manage patient care over a longer period of time across numerous care settings and participating providers. Indeed, the true clinical measures to support these activities have not yet been developed.

Extensive expansion of the BPCI initiative will therefore need to be very carefully considered from both provider financial and patient clinical risk perspectives. Given modest provider participation in BPCI during Rounds 1 and 2, an expansion only in the form of a voluntary “Round 3” makes sense. The Lewin Group, which was contracted by CMS to evaluate the BPCI initiative, has only published one report evaluating the preliminary results from the first year of the BPCI initiative (released in February 2015),2 and the implications of its findings for expansion of the BPCI initiative are unknown. This evaluation requires at least several more years of maturation and learning before enough is known about the impact of the BPCI initiative on providers and patients to consider scaling the program.

Given that regional variation in health care delivery is most pronounced in post-acute care (PAC) delivery, regional representation in expansion should be encouraged and regional variation should be incorporated into evaluation activities. As several peer-reviewed articles published in recent years on geographic variation in health status3,4 as well as a recent Institute of Medicine (IOM) report on within-hospital variation5 indicate, regional variation in PAC delivery is complex and its relation to the BPCI initiative requires further exploration. Real geographic differences in health status across regions and their relationship to how the PAC industry is organized and operates must be better understood to ensure appropriate payment rates are set and that patient’s access to care is preserved. Consequently, mandatory expansion of the BPCI initiative within one region or across regions without fully understanding the determinants of regional variation in Medicare spending could be presumptive.

**Episode Definitions**

**Key Questions:** Should episode definition refinements be made with respect to how the episodes are categorized, the duration of the episodes, and which services are included/excluded? Should CMS consider using standardized patient assessments to categorize post-acute episodes rather than the acute care hospital discharge diagnosis?

**Episode Classification for Model 3.** In defining episodes under the BPCI initiative, policymakers must recognize that Medicare Severity Diagnosis-Related Groups (MS-DRGs) are

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generally poor predictors of patients’ post-acute care needs and cannot be consistently relied upon for post-acute placement decisions. MS-DRGs, in identifying diagnoses and procedures delivered in the acute care hospital setting, do not relate to the skilled nursing needs, functional limitations, or therapy/rehabilitation focused on in PAC settings after hospital discharge. Using MS-DRGs as the basis of episode assignment may be appropriate for Model 2 episodes that begin with an acute care hospitalization. However, there are issues with using MS-DRGs as the basis for defining Model 3 episodes, which begin with a stay in a post-acute care setting.

First, and most directly, Model 3 episode initiators have found it difficult to obtain the anchor MS-DRG for a given patient in a timely manner, that is, from the acute care hospital that the patient was discharged from prior to the post-acute stay. Second, in cases where it is possible to timely obtain the MS-DRG, the reason for post-acute care admission may be very different from the reason for the acute care stay (e.g., a patient requiring post-discharge recovery for simple pneumonia or requiring ventilator support following an inpatient stay for cardiac surgery). Third, even when the reasons for the acute admission and post-acute admission match, MS-DRGs are still not a strong predictor of the type of post-acute care needed because they do not account for functional needs (a primary component of post-acute discharge planning).

Therefore, the current BPCI episode definition may need to be modified for Model 3 participants for the following reasons:

- MS-DRGs are not available in a timely manner to determine BPCI qualification;
- A given Model 2 MS-DRG may not be the primary reason for the patient’s need for post-acute care services; and
- MS-DRGs do not take into account functional status, which is an important indicator for determining patients’ post-acute care needs.

Because Model 3 focuses exclusively on post-acute care delivery, and because post-acute care needs are poorly correlated with MS-DRGs, Model 3 episodes should be defined according to the patient’s needs for PAC, as patient outcomes could be negatively affected by the lack of clinical coherence between MS-DRGs and PAC. This dissonance highlights the importance of a uniform assessment tool. Although a uniform PAC assessment tool was authorized to be developed under the IMPACT Act of 2014, other tools will be required in the near term to build a bridge between MS-DRGs and PAC, or across care delivered in different PAC settings.

A number of organizations in the private and public sectors have developed short form hospital discharge screening tools for this purpose. Similar tools could be considered for use under the BPCI initiative, granted that their ease of use and implementation are not overly burdensome for providers and administrators. The B-CARE tool, which reflected a shorter version of the CARE tool (developed by CMS as a uniform PAC assessment tool), was initially developed for Round 1 of the BPCI initiative but was not implemented likely due to the administrative burden it would have placed on providers at the point of patient discharge. However, if a tool does not provide enough capacity to precisely measure and determine functional ability, then it will risk reducing the clinical power of existing assessment instruments.
As an alternative to a uniform PAC assessment tool, CMS could consider developing and using an episode categorization system that crosswalks the various measurement systems currently in use by prospective payment systems for PAC (e.g., Resource Utilization Groups (RUGs) in SNFs, Case Mix Groups (CMGs) in IRFs, and Home Health Resource Groups (HHRGs) in home health agencies). Under this alternative, Model 3 episodes could be initiated under one of the existing PAC PPS case mix systems, and a common functional status scale could be developed from existing measurement tools. For instance, a recent report by Dobson | DaVanzo showed that a simple scale across the current functional assessment tools used in IRFs, SNFs, and HHAs could improve the R^2 power of a regression models’ ability to predict episode expenditures by 20%.

BPCI Model 2 participants have the option of selecting episode lengths that begin with the admission to the hospital and end 30, 60, or 90 days following discharge. Similarly, BPCI Model 3 participants have the option of selecting episode lengths that begin with the admission to the post-acute provider and end 30, 60, or 90 days following the admission. Currently, Models 2 and 3 episode initiators have the option of selecting different episode lengths for each of their selected clinical conditions.

Prior research has shown that the difference in average Medicare payments across episode lengths varies by MS-DRG. For instance, a Dobson | DaVanzo study^6 found that among certain MS-DRGs, the vast majority (over two-thirds) of Model 2 episode payment occurs within seven days following the anchor hospitalization, such as MS-DRG 247 (percutaneous cardiovascular procedure with drug-eluting stent w/MCC). Among other MS-DRGs, such as MS-DRG 291 (heart failure and shock w/MCC), Medicare episode payment within seven days accounts for less than half of payment in a 90 day episode and is more dispersed over the 90 days following hospital discharge. Since there has been little research performed to date on optimal episode lengths and there is significant variation in episode costs depending on episode length, we continue to support allowing participants the option of selecting episode lengths that they deem appropriate for managing patients through the course of the episode.

However, CMS should also consider allowing episode initiators to choose longer episode periods for certain episodes for patients with multiple chronic conditions, where optimal outcomes may not be realized for 6 to 12 months.

Models for Expansion

**Key Questions**: Should CMS consider one or more of the current BPCI initiative models for expansion? Should CMS expand several or all of the models on a similar timeframe, or one at a time?

As CMS considers whether or not to focus an expansion of the BPCI initiative on one or more of the four models currently being tested, there are many issues surrounding the selection

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of models—and specific types of episodes within models—that need to be addressed. These issues include:

- **Market uptake of Models 1 and 4.** The limited participation of providers in Models 1 and 4 suggest that continued emphasis on these models is not worth the opportunity cost of devoting less time and energy to Models 2 and 3.

- **Surgical vs. medical MS-DRGs.** Because surgical MS-DRGs tend to have a greater proportion of total episode spending occur within the acute care hospital—as opposed to PAC settings following hospital discharge—and have less variation in total episode spending over greater periods of time, CMS could focus expansion of Model 2 on surgical MS-DRGs and Model 3 on medical MS-DRGs.

- **PAC as a “carve out” of Model 2.** Model 3, which only includes care delivered after hospital discharge, could be thought of as a “carve out” to Model 2. In this framework, the PAC component of Model 2 could be sub-capitated within the episode. Several third-party organizations operating as conveners within the BPCI initiative are currently pursuing business models under a similar framework, although it is unknown at this time whether and how such an arrangement will work in practice.

- **Precedence rules.** The current precedence rules are very concerning and should be adjusted to create a level playing field for hospitals. At present, episodes are automatically attributed to a physician group episode initiator, even if the physician of a hospital episode initiator is also involved in the care. This puts hospitals at a distinct disadvantage and encourages physician groups to enter the program without the hospitals, causing further fragmentation. We believe a more equitable process to attribute the patients to an episode initiator would be to consider the role of the physicians who are part of the hospital group compared to those of the physician group, or developing a plurality of services model more closely aligned with MSSP.

Regardless of the method, hospital groups should be allowed as conveners and put on an equal playing field with physicians. Hospital systems have much to offer in terms of capital, PAC coordination (e.g., nurse navigators, care managers), electronic medical records, outpatient rehabilitation therapies, diagnostic testing facilities, long-standing quality reporting and improvement initiatives, data analysis capabilities and comprehensive financial metrics. These unique clinical, functional, and organizational strengths position hospitals to bring providers together in new payment and delivery arrangements that help ensure BPCI’s success. It is imperative that CMS establish precedence rules that recognize the central role hospitals play and encourage their participation on the same level as physicians. In that vein, CMS should apply to physicians who participate as episode initiators the same gainsharing cap that applies to physicians who gainshare with Model 2 hospital participants.

- **Limited national expansion of low variation episode types.** Certain episode types that are less sensitive to regional variation, such as hip and knee replacement, could be the focus of a national voluntary expansion of BPCI while regional variation in health status and other factors that affect differences in health spending are further investigated.

A concern for expanding BPCI Models 2 and 3 is that episode costs vary dramatically depending on the PAC placement of the patient following the acute hospital stay. Many of these
cost differences, for what could be essentially the same types of patients, may be due more to the “siloed” nature of Medicare’s PAC payment systems and conditions of participation requirements rather than a reflection of efficient patient treatment rendered by providers. BPCI expansion should provide strong incentives for the clinically appropriate and cost effective placement of patients into PAC settings and allow PAC providers to fairly compete with one another on the basis of costs and quality. Any incentives to alter patterns of care across PAC settings must account for differences in patient severity and functional status as measured in a standardized way across those PAC settings.

Currently, existing conditions of participation restrict fair competition across PAC providers. One example is the 3 hour therapy rule for IRFs. According to the 3 hour therapy rule, Medicare requires that at the time of admission, the patient must receive and benefit from three hours of therapy per day for at least five days per week. If patients are unable to tolerate 3 hours of therapy for 5 days each week, they would not qualify for IRF care. Another example is that IRFs and LTCHs are required to have higher staffing ratios with more frequent patient contact by physicians than other PAC settings. In addition, IRFs and LTCHs must meet stringent Federal hospital conditions of participation, among other strict Federal and state hospital licensing, and other regulatory requirements – other PAC settings do not.

Each PAC setting also has unique requirements for the proportion of patients with certain clinical conditions (i.e., the IRF “60% Rule”) or level of clinical severity as measured by average hospital length of stay (i.e., the LTCH “25% Rule”); home health requires a physician certification that the patient is “homebound” in order to be admitted for these services. Some of these regulatory requirements could be alleviated in the form of waivers. Without addressing the underlying difference in cost of providing clinically appropriate care across PAC settings, however, the BPCI initiative could effectively take the form of “site neutral payment” that risks becoming a site preference policy simply seeking to place patients in the setting with the lowest spending, independent of clinical appropriateness. If left unaddressed, these regulatory differences have the potential to negatively impact patient referral patterns and patient access to clinically appropriate care in certain types of settings as well as restrict fair competition across PAC providers.

Roles of Organizations and Administering Bundled Projects

**Key Questions:** What roles should organizations, such as health care providers, suppliers, and other entities, serve under an expanded model? What types of relationships and arrangements, financial or otherwise, would assist participants with care transformation in an expanded model? Will relationships encouraged under an expanded model have unintended consequences, and if so, what?

Currently under the BPCI initiative, third-party organizations that do not deliver health care services to beneficiaries under the episode are permitted to operate as awardee conveners, taking financial risk for spending under the episodes for which they are participating. The role of

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third-party organizations in payment bundling is not well understood at this time because these organizations—as well as the providers with which they are working—have limited experience in managing and administering bundled payments. However, given the large role these organizations are already playing in the BPCI initiative, there are a number of potential unintended consequences of an expansion.

For instance, third parties might be rewarded too much (e.g., 2% of the target price, plus shared savings) and hospitals and other providers rewarded too little after providing a discount of 2-3% to CMS, a financial relationship that could be problematic for providers. Hospitals must be able to recoup their investments from the BPCI initiative, otherwise short-term improvements achieved under the BPCI initiative may undermine larger goals, such as chronic disease management and population health. If provider savings are transformed into convener profits, then the current financial arrangement may be unsustainable since the entities delivering care would be unable to fund care coordination and care transition activities.

In addition, third-party organizations with a substantial financial investment and share of the risk under the BPCI initiative may play a large role in clinical decision-making for providers (such as insurance companies), which would break an important link between patients and the clinicians delivering their care. Along those lines, providers contracting with risk-bearing awardee conveners have little incentive to fully engage in true care delivery innovation as they do not bear the risk. This is counter to CMS’s stated intent of bundled payment: to bring providers together to fundamentally change the provision of care in order to increase the value and patient experience of care.

The role of community and social service providers must be recognized as an important aspect of the full continuum of health care. If the community and public health implications of expanding BPCI are not carefully considered, then the BPCI initiative could have adverse effects on population health. In addition, the funding mechanisms for these community and social service organizations and how they relate to participating providers need to be addressed. Such organizations take on even more importance as the frail elder population continues to expand rapidly over the next several decades.

Ultimately, care transformation must be carefully considered and implemented. It is essential that the savings generated adequately cover the costs of investing in and implementing changes in care delivery. The possibility of unintended consequences is thus real and could be substantial. If third parties are to take risk and draw down on provider savings, these arrangements must allow providers to accumulate adequate investment and operational capital to effectuate and sustain changes in the delivery system. If not, providers run the risk of not having enough savings remaining to invest in care redesign.

Accordingly, CMS should attempt to maximize voluntary participation in the BPCI initiative by creating incentives and opportunity while protecting providers against too much risk and uncertainty. Third-party organizations potentially represent an innovation in the delivery of care under episode-based payments, but if left unchecked these organizations could dominate the landscape and have adverse effects on patients as well as providers.
Setting the Bundled Payment Amounts

**Key Questions:** Should CMS base payments on regional episode experience or set all payments prospectively under model expansion? Should the same episode discount percentages be applied to all episodes, or varied based on care redesign opportunity within the episode? What methodologies should be used to determine discount percentages? Should payments be rebased annually, or on another timeframe? Should CMS consider a different methodology for setting bundled payment amounts?

The methodology that CMS uses to set bundled payment amounts as it considers an expansion of the BPCI initiative must balance savings to the Medicare program with provider financial stability and patient access to care, and has important implications for the future sustainability of bundled payments and value-based payments generally.

Currently, CMS sets target prices using provider-specific historical spending data from 2009 through 2012 with a regional blend for low-volume clinical conditions and reduced for specific discounts to Medicare. All providers rendering services to a beneficiary in a BPCI episode, including episode initiators, continue to be paid on a fee-for-service basis for actual care delivered. These fee-for-service expenditures are later reconciled against target prices over a three-quarter adjustment timeframe. After reconciliation with target prices is performed, gain sharing payments are made, and any savings (or losses) paid from (or to) CMS are shared with the BPCI network.

There are a number of benefits to both CMS and providers by continuing this “virtual” bundled payment system of fee-for-service payments with reconciliation against the target price. At the same time, as noted below, CMS may want to permit targeted prospective payment options, on a voluntary basis, for PAC services and episodes specifically under Model 3 of BPCI. Some of these benefits include:

- Providers across the country do not have enough experience with bundled payments to begin operating under prospective payment that would require awardees to negotiate rates and make payments to all providers rendering services throughout the episode of care. In addition, CMS does not have enough experience setting prices for these types of episodes to create a new prospective payment system that incentivizes efficient care delivery while maintaining adequate payment amounts in a predictable manner.

- By paying providers on a fee-for-service basis, CMS will continue to generate claims data that will allow for the analysis of trends in utilization and spending within episodes over time. Medicare fee-for-service claims data are widely recognized as a complete and accurate longitudinal source of information on health care spending and utilization; this lies in contrast to encounter-type data collected under other forms of bundled payment, such as global or capitation-type payments, which lack information on service-level spending, are often incomplete and/or of unknown quality. The lack of available claims data in the Medicare Advantage program and the range of data quality issues across states under Medicaid managed care are just two examples of how the transition from fee-for-
service to capitated payments can lead to challenges in future data analyses on cost, quality, and patient outcomes that are required for mid-course policy adjustments.

- Fee-for-service payments maintain a predictable cash flow to all providers participating in the BPCI initiative. In addition, fee-for-service payments made for the actual care delivered hold downstream providers harmless (aside from possible gain sharing risks) from the episode initiator for spending in excess of the target price, which is necessary while issues relating to the administration of bundled payments from CMS to awardee conveners to downstream providers are resolved over time.

- While CMS should continue fee-for-service payments as the predominant option under the BPCI initiative, CMS should also permit the testing of different options for prospective payment for targeted episodes, specifically with respect to PAC services under Model 3. The reason this is important to test is that, under the current fee-for-service payment system, certain PAC payment systems (e.g., for LTCHs and IRFs) can trigger high payments that could discourage use of these services in the context of an episode, even when the services are clinically appropriate and necessary. The testing of different payment models—for example, by allowing for a prospective rate for those BPCI participants willing to accept this risk—would produce very useful information about the use of different PAC services for specific patient populations that might not otherwise be tested under a retrospective model. As noted elsewhere, the waiver of fee-for-service rules would be a critical element of this type of model.

Under an expansion of BPCI, CMS should consider refinements to its methodology for determining target prices, which changes on a quarterly basis, based on national trends in episode costs from the 2012 base period to the quarter of performance. Reconciliation is performed at least five months after episodes are completed and awardees do not know what the actual target price will be until reconciliation. We do not believe it is appropriate policy to hold providers at risk for prices that are unknown until after the episodes are “complete”.

This current price setting methodology poses a challenge to providers due to the changes in pricing over a subsequent three-quarter “run-out” timeframe. Target prices could be set annually and made available to providers prior to the beginning of the year, which is consistent with other Medicare payment systems. Without more information on the degree to which these target prices change quarter to quarter, one does not know how volatile prices will be at the awardee-convener level. Setting and updating target prices on an annual basis, such as the annual baseline spending targets for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP), would allow for providers to better implement efficient care redesigns linked explicitly to established payment rates for each type of episode. CMS would also be able to reduce its administrative burden of recalculating and reconciling target prices on a quarterly basis if it transitioned to an annual payment setting methodology comparable to the other Medicare prospective payment systems. The annual payment setting approach would also reduce the possibility for errors being made in the CMS rate setting process.

Second, provider-specific target prices for awardees in low-cost market areas do not create a strong incentive for providers who operate in these markets to participate in the BPCI
initiative. Low-cost areas allow only a limited opportunity for providers to make additional gains in efficiency that could produce savings. CMS could consider the following options for adjusting target prices across areas:

- **Applying different discount factors across high and low cost areas.** CMS could reduce the required discounts for providers in low cost areas and potentially increase discounts in high cost areas so that the CMS target savings amount is still achieved in the aggregate.

- **Provide additional incentives in the payment-setting methodology for providers.** For example, a series of quality measures could be incorporated into the payment system such that the discount off of the target price is reduced for providers delivery high-quality care. Again, holding the overall CMS target amount budget neutral.

- **Calculate and apply regional trending factors instead of national trend factors.** These trends would implicitly adjust for differences in the health status of patient populations across areas and providers, existing supply of post-acute care providers in different market areas, local infrastructure needed to manage and coordinate care across the continuum of acute care and PAC, and other factors that affect episode spending. National targets to reduce regional variation in expenditure levels could be blended in over a longer adjustment period.

CMS needs to allow more time for providers to operate under bundled payments, and for analysis of spending trends, patient outcomes, and access to care before considering a transition to nationally set target prices or target price adjustments weighted toward national rather than historical or regional updates.

Finally, existing risk adjustment tools may not be sophisticated enough to adequately address the frail elderly population. This population—which typically has two or more limitations in activities of daily living (ADLs) and on average has over two years of self-care disability at the end of life—is expected to grow substantially over the next several decades. The clinical and functional needs of the frail elderly are much higher than the average Medicare beneficiary, and therefore more consideration should be given to how payments are risk adjusted for this population to account for greater resource use. In the meantime, considerations can be technically made to compensate for inaccurate risk adjustment.

In addition, further research should be performed on refining the patient classification system for BPCI Model 2 and 3 episodes that include post-acute care services. MS-DRGs do a good job of explaining differences in patient resource use for acute care services. However, MS-DRGs are not well related and as a result do not adequately explain post-acute care needs or resource use. Studies have found that MS-DRGs by themselves are an inadequate unit of payment for post-acute care payment bundles.8 Also, MedPAC found that only 8% of the variation in charges for 30-day PAC-only episodes could be explained by the MS-DRG from the prior acute hospital stay.9 Also, MS-DRGs do not take into account the patient’s functional needs.

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status, which is an important factor in post-acute care placement decisions. If MS-DRGs are continued to be used as the BPCI episode classification system, there may be a need to further stratify MS-DRGs based on patient functional status.

The current system used by CMS to set payment amounts leaves providers with a great deal of uncertainty in the price they will be receiving for services delivered to Medicare beneficiaries. Refinements to the process for setting target prices that increase transparency, reduce volatility, and improve predictability will encourage participation in the BPCI initiative among more providers and will contribute to the longer-term sustainability of the program.

Mitigating Risk of High-Cost Cases

**Key Questions:** What are strategies to mitigate the risk of high-cost cases to ensure appropriate payment for these episodes under model expansion, such as through outlier or other policies, while encouraging high-value, coordinated care for these cases? Should CMS consider an outlier pool with specific payment policies, such as under the IPPS and OPPS?

Given the savings targets set by CMS under the BPCI initiative, as well as additional points taken out of the target price by third-party conveners, providers face a great degree of risk for high-cost cases. For a low-volume provider, one outlier case could eliminate all achieved savings against a target price and incur substantial costs. Risk corridors or outlier payments are necessary to reduce the possibility of significant financial losses to providers for high-cost cases.

The potential for high-cost cases is also an important consideration in whether and how to expand the BPCI initiative, as high-cost cases pose a greater risk to episode types and episode initiators with a low volume of cases. Episode types with the greatest volume are better candidates for expansion as they allow providers to smooth the risk of bundled payments over a larger number of cases. This is likely why so many BPCI conveners are choosing orthopedic surgical MS-DRG categories as they show less expenditure variance across episodes than medical MS-DRGs.

Administering Bundled Payments

**Key Questions:** What is the feasibility of different payment approaches under the various models, including the administrative capacity for some organizations to pay others for care delivered under the episode and/or to share payments at reconciliation? What operational and policy considerations would need to be addressed under the possibility of paying an awardee convener the bundled payment if the entity did not deliver health care services to beneficiaries under episodes in an expanded model?

The designation of a single entity to receive prospective bundled payments presents a number of challenges. The change to the way in which Medicare providers bill for and receive payments under BPCI will require a lengthy period of adjustment for BPCI providers and conveners. A single entity could, in effect, become more like an insurance company that negotiates payment rates, controls volume, and administers payments to providers. The degree to which providers have the administrative and managerial capacity to receive and distribute
bundled payments to downstream providers is unknown, but the pool of awardee conveners with this capacity is likely highly limited.

In addition, the ability of providers to continue competing in the market could be adversely affected by the designation of a single entity to control a payment bundle—particularly if this entity were to be chosen by CMS, rather than through business relationships negotiated by providers in the market. A single entity, depending upon its size and concentration in a given marketplace, could create “narrow networks” that exclude certain providers from participating in the BPCI initiative or control the prices paid for services delivered under a bundle.

If CMS chooses to designate a single entity to receive prospective bundled payments, which will then be distributed to other downstream providers, there will be a number of issues to consider, including:

- How standards or criteria will be determined for whether an entity qualifies to receive prospective bundled payments;
- How providers downstream from the single entity will be protected from “arbitrary” or seemingly arbitrary payment withholds and delays;
- How small awardees will be incorporated into the policy, as they have less capacity to administer such payments than larger, more sophisticated organizations;
- How third-party awardees will be regulated as intermediaries between CMS and participating providers;
- How patients will be protected against limited access to care that may result as an unintended consequence from challenges in payment administration or patient “stinting” of care more generally; and
- How health care systems and other providers will be paid under a prospective bundled payment system.
- How clinical decisions could be influenced by a third-party awardee’s incentive to reduce cost as aggressively as possible.

CMS needs to exercise caution in considering whether and how to designate a single entity to administer bundled payments, focusing on the protection of patient access to a broad range of providers in order to ensure fair competition among providers for BPCI patients in a vibrant marketplace.

Data Needs and Use of Health Information Technology

**Key Questions:** What types of data and functionality are needed in the marketplace in order to expand this type of model (e.g., EHRs, quality measurement)? How can health information technology be used and encouraged in coordinating care across care settings, including PAC? How should CMS include SNFs, IRFs, LTCHs, and HHAs, which currently do not utilize health information technology and health information exchange at an advanced level, in the coordination of care across acute care hospitals and PAC providers?

Downstream providers need to know a patient’s MS-DRG immediately upon discharge to a PAC setting, in order to determine whether or not they are participating in the BPCI initiative.
case and to which episode the patient is being attributed. For providers participating in Model 2, there is an incentive for the hospital to use as much clinical information as possible to assist in discharge planning and transmission of this information to downstream PAC providers. Although hospitals do not officially know which MS-DRG a patient is grouped into until the billing process is complete, the hospital is gathering the diagnosis and procedural information during the patient’s stay that comprises the MS-DRG, so temporary MS-DRG assignments are common.

However, if PAC systems participate in Model 3 and MS-DRGs continue to define Model 3 episodes, downstream PAC providers need to know their patient MS-DRGs in as close to “real-time” as possible. Without direct hospital participation in Model 3, gaining this information would be challenging.

Under BPCI, discharge planning is likely to commence upon patient admission to the hospital. Anecdotal information suggests that many hospitals have ongoing “working definitions” of MS-DRGs as patients move through the hospital, and could therefore share this information with downstream providers soon enough to inform care transitions and improve clinical practices. However, any requirement that hospitals transmit working definitions of MS-DRGs to PAC providers in a standardized way should not unduly burden hospitals with additional administrative requirements.

The BPCI initiative should consider how to improve the data link between hospital MS-DRG and the clinical conditions being treated in follow-on PAC stays. One mechanism would be through enhanced electronic sharing of information (between clinics, hospitals, PAC settings, community health centers, etc.), although interoperability of electronic health record (EHR) systems could pose a substantial obstacle.

Given the imperfect relationship between hospital MS-DRG designation and PAC needs, policymakers, researchers, and evaluators should identify what consistent clinical and functional status data are needed by providers at the point of care (i.e., missing from claims data) in order to supplement existing administrative data. Short forms that can be quickly completed by providers may be adequate.

BPCI participants will need some means of linking monthly claims data reports from CMS with real-time clinical data stored in EHRs or other information systems. Without this link, it will not be possible for providers to increase efficiency in the delivery of care while simultaneously improving patient outcomes. Data vendors will primarily be challenged on this problem; however, addressing these issues assumes that an infrastructure can support the sharing of the ‘correct’ data and raises additional questions about whether operational-level changes can realistically be achieved in a short period of time on a broad scale.

With the broader goal of the BPCI initiative to transform care delivery, CMS should also consider providing beneficiary-level claims data on a regular basis—as it does under BPCI—to any willing provider that is participating in payment and delivery reform initiatives. These data will ultimately be necessary to support true reform of the delivery system and improved patient outcomes under any alternative payment model.
Quality Measures and Payment for Value

**Key Questions:** *What quality measures can be applied to episodes? What approaches can be used to incorporate value-based payment into the BPCI initiative (e.g., reducing the discount percentage for high quality care or increasing it for low quality care)?*

In order to assess quality of care under the BPCI initiative, episode-specific quality measures will need to be developed that address a range of issues, including:

- The need to ensure that pressures to reduce cost do not result in the elimination of necessary care;
- A link to continuity of care quality measures, which currently do not exist;
- The need for consistent functional status measures across PAC settings for base risk adjustment and change in functional across time (e.g., “CARE tool” measures);
- The relationship between episode-specific quality measures and other value-based purchasing arrangements that reward or penalize providers financially for certain patient outcomes, which have the potential to “double count” penalties across new innovative payment systems (such as all-cause hospital readmission rates in the fee-for-service program as well as in the Medicare Shared Savings Program);
- A link between quality improvement protocols (e.g., Six Sigma) and quality measures; and
- Review of proposed quality measures and measure sets by the recognized consensus-based multi-stakeholder entity (the National Quality Forum), prior to the measures being included in rulemaking.

Quality measures developed for the BPCI initiative may also need to link to emerging third-party administrative and financial arrangements.

Transitions from Medicare FFS Payment to Bundled Payment

**Key Questions:** *What is the need for, and what should the parameters be of, a transition period from Medicare FFS payment to bundled payment under an expanded model (e.g., length of transition, how a transition would be made)?*

The traditional Medicare fee-for-service payment system is important in underpinning a major component of the nation’s health care delivery system. Using fee-for-service as a framework, CMS has introduced numerous initiatives to improve quality and value in the health care delivered to Medicare beneficiaries, and at the same time growth in per capita Medicare spending has fallen dramatically over the last several years; the HHS Assistant Secretary for Planning and Evaluation recently reported that the growth rate fell to 0.2% in 2013. The fee-for-service system allows for predictability in pricing, is relatively simple to administer, and

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provides beneficiaries with flexibility in choice of providers as well as broad access to range a
providers.

Movement away from this basic system too quickly and without careful consideration of
the complex issues in care delivery, pricing, administration, and patient access that must be
addressed in payment bundling or other value-based payment systems could have unintended
consequences for providers and patients alike.

It will also be important to maintain FFS administrative claims as the BPCI initiative is
considered for expansion, in order to capture utilization as well as quality measures within
episodes, in order to determine the impact of bundled payments on the care delivery process.

Any transition must ensure that providers have adequate financial strength to initiate,
develop, and implement care transition strategies on an ongoing basis.

The capital investments required to design continuity of care and care transition
improvements, as well as the variable costs required to support the requisite staff needed to
implement and maintain quality improvement protocols, must be paid for otherwise sustained
improvements and/or new quality initiatives may not be achieved or undertaken. CMS will need
to carefully consider how rewards from improvements in efficiency will be split between
providers, other third parties, and the Medicare program.

Wage Index

The FAH supports most of the changes CMS has advanced with respect to the Medicare
wage index. However, there are two components of the Proposed Rule, as well as certain
elements of the wage index generally, that FAH believes require comment. Those matters are
discussed below.

III.C. Verification of S-3 Wage Data

With respect to the wage index process generally, FAH takes issue with CMS’s practices
for determining what hospitals should and should not be included in the wage index PUF.
Specifically, the FAH is aware of numerous instances in recent years in which CMS has made
unilateral decisions to exclude certain facilities from the wage index calculations on the grounds
those facilities had “excessive” or “aberrant” labor costs. CMS acknowledges this to some
extent in the Proposed Rule when it indicates:

For the proposed FY 2016 wage index, we identified and excluded 93 providers
with aberrant data that should not be included in the proposed wage index. If data
elements for some of these providers with aberrant data are corrected, we intend
to include data from those providers in the final FY 2016 wage index.

80 Fed. Reg. at 24,464 col.2. In this regard, the FAH maintains that, unless and until the agency
adopts clear, publicly announced standards for making these kind of determinations, CMS does
not have the authority to exclude facilities from the PUF for having “excessive” or “aberrant”
costs.
CMS’s decisions regarding the wage index are subject to review under the federal Administrative Procedure Act ("APA"). See, e.g. Atrium Med. Ctr. v. United States Dep’t of Health & Human Svcs., 766 F.3d 560, 566. Agency action is invalid under the APA where, among other things, the agency acts in excess of its statutorily delegated authority or otherwise engages in arbitrary and capricious conduct. See Am. Bus Ass’n v. Slater, 231 F.3d 1, 7-8 (D.C. Cir. 2000). Given these standards, CMS’s continued exclusion of the hospitals from the PUF on the grounds those hospitals have excessive or aberrant labor costs could potentially be challenged in court on multiple grounds.

First, there is no statute, regulation or manual guidance vesting CMS with the power to exclude a hospital or hospitals from the PUF based on a unilateral determination that the labor costs incurred by that hospital are excessive or unusual. In this regard, the FAH recognizes that CMS has before responded to comments from the industry regarding its ability to exclude hospitals from the PUF. On that occasion, CMS indicated that its authority to delete certain hospitals from the PUF if they have “extremely” or “unusually” high labor costs (see the 2015 IPPS Final Rule at 79 Fed. Reg. at 49965) derives from 42 U.S.C. § 1395ww(d)(3)(E), which is the statute that establishes the wage index generally. Respectfully, the FAH maintains that this statute does not support the agency’s position.

The relevant statute says nothing about CMS being able to exclude data from particular facilities from the wage index determination for any reason, let alone for having “excessive” labor costs. See 42 U.S.C. § 1395ww(d)(3)(E). Although the statute does confer upon CMS discretion to establish the wage index, that general grant of power cannot be read to include the authority to exclude particular facilities from the wage index based on an unannounced, unclear standard as to excessive costs. See Catholic Health Initiatives v. Sebelius, 617 F.3d 490, 498-500 (D.C. Cir. 2010). In short, since CMS’s exclusion of particular hospitals from the PUF on the grounds those facilities have “excessive” or “aberrant” costs is not rooted in any express, statutory grant of authority, it is not a valid exercise of the agency’s discretion.

Second, even if the authority conferred on CMS by 42 U.S.C. § 1395ww(d)(3)(E) is arguably broad enough to encompass the exclusion of particular facilities from the wage index calculation, the FAH contends that the manner in which CMS is exercising that authority is improper. Under the APA, where an agency rule goes beyond merely an interpretation of the relevant enabling statute, that rule cannot be enforced unless until it has been promulgated through a formal notice and comment process. See Catholic Health Initiatives, 617 F.3d at 494. In this instance, since the wage index statute does nothing more than grant CMS general authority to determine the wage index, a policy calling for the exclusion of facilities from the calculation found to have “excessive” costs cannot reasonably considered a mere “interpretation” of the statute. Instead, CMS is applying a substantive rule not expressly contemplated by the statute and, as such, was required to adopt that rule through formal procedures. There has been no public and notice comment process related to CMS’s purported policy calling for exclusion of extremely high cost facilities from the wage index.

Third, CMS’s exclusion of certain hospitals from the PUF is an abuse of discretion because the agency has provided no standard for when a facility’s labor costs are “excessive” for wage index purposes. It is arbitrary and capricious for the agency to make wholly unilateral decisions about what constitutes excessive costs without affording providers any kind of
advanced notice or guidance as to what potentially would make their respective costs qualify as excessive or unusual. Hospitals cannot modify their practices to potentially avoid a determination that their costs are excessive without knowing what exactly CMS considers excessive.

Further, CMS’s current approach to evaluating hospital labor costs is inconsistent with more general Medicare reimbursement principles. CMS has promulgated instructions as to how providers are to report labor costs for wage index purposes. See Medicare Provider Reimbursement Manual, Part 2, § 4005.2. These instructions state, among other things, that “the amount reported for wage-related costs must meet the ‘reasonable cost’ provisions of Medicare.” See id. Medicare regulations, in turn, establish that a hospital’s actual costs should be considered “reasonable” unless substantially out of line incurred by comparable providers. See 42 Code of Federal Regulations § 413.9(c)(2). Under this regulation, the burden is on CMS to provide that a hospital’s costs are out of line before it can exclude those costs from the reimbursement calculation. See id. The FAH is not aware of any factors indicating that CMS’s decisions as to the allegedly “excessive” nature of the wage costs of particular hospitals meet the regulatory standards described above. Therefore, the policy CMS is applying to exclude certain providers from the PUF is unreasonable and shortsighted.

Additionally, as a more practical matter, the FAH notes that the MAC desk review process is already designed to address any aberrant data for an individual hospital’s salary and hours and its wage related costs. If this process, under which the MAC is working on the ground level with particular providers, is completed without the MAC identifying any aberrant costs, it seems incongruous that CMS could then potentially find such aberrant cost through a separate review process. Yet, the FAH understands that exactly such scenarios have played out. Therefore, in addition to the other flaws discussed above, CMS’s current policy for evaluating hospitals for inclusion in the PUF also undermines the Medicare program’s already existing desk review process.

This issue of critical importance because the exclusion of particular providers from the PUF can not only significantly impact the excluded providers, but all providers that are within the same geographic area, for wage index purposes, as the excluded provider or providers. The exclusion of just one facility can result in wage index swings of millions of dollars for that and other facilities. The FAH believes that the potential significance of these decisions highlights why they need to be made by CMS in a reasoned, consistent and transparent manner.

For all the foregoing reasons, the FAH urges CMS to discontinue its practice of excluding particular facilities from the PUF for having aberrant or excessive costs until, at a minimum, the agency adopts clear standards for what will be considered excessive or aberrant costs through a public notice and comment process.

III. N. Changes to Wage Index Timetable for 2017 and Subsequent Year

In the Proposed Rule, CMS states that it intends to make changes to the current timetable for developing wage index data for a given year. 80 Fed. Reg. at 24475-24477. The proposed timetable largely tracks the timetable that CMS adopted as part of the 2015 IPPS Final Rule for the 2017 wage index (see 79 Fed. Reg. 49987-49990), with the main additional modification
coming with respect to reporting of pension costs. Under the proposed timetable, CMS will issue preliminary wage index data in May of each year and providers will have until the first week of September to request revisions to the wage index “Public Use File” or “PUF.” See 80 Fed. Reg. at 24476. While the FAH recognizes that part of CMS’s rationale in adopting the proposed time table is to allow hospitals more time to review and correct preliminary data in the PUF and appreciates the agency’s efforts in this regard, the FAH believes the proposed time table still is not optimal for that purpose.

The FAH supports the general concept of altering the wage index development timetable. As was the case with the timetable announced in the 2015 IPPS Final Rule, the FAH supports CMS’s proposal to release wage index data in May. The FAH does not support, however, CMS’s proposal to set the deadline for hospitals to request corrections to the PUF in early September. The FAH believes that the deadline to request wage index data adjustments is too accelerated and will not give hospitals and other wage index stakeholders sufficient time to adequately “scrub” the data released by CMS. As an alternative, the FAH proposes that, as with FY 2016, CMS continue for FY 2017 with an early October deadline for requesting adjustments, or, if CMS insists on moving the deadline up, setting it for late September. Setting the deadline in October would be preferable to an early September deadline when many hospital personnel (as well as CMS and MAC personnel) are vacationing or have just returned from time off and therefore have even less resources available than normal to deal with demands of ensuring their respective wage index data is accurate. An October deadline to request adjustments mitigates this issue significantly by allowing more time for hospitals to scrub data and MACs to complete required desk reviews.

In addition, in conjunction with revising the wage index development timetable, the FAH suggests that CMS consider additional amendments to wage index data in support of the following two objectives: First, provide MACs with direction to notify state hospital associations of aberrant data. Currently, communications between the MACs and hospital associations is limited to information about facilities that do not respond to requests for data. The FAH believes that involving hospital associations in effort to correct aberrant data will help ensure the accuracy of the wage index.

Second, along with making hospital associations aware of wage index data errors, CMS should provide additional guidance to MACs and wage index stakeholders as to the process for correcting erroneous data errors, including a timetable for such making such corrections. This is necessary because the notification of hospital associations would be after the deadline for individual hospitals to request data adjustments. The FAH believe CMS should establish clearer procedures for hospital associations and/or providers to follow in correcting any data problems noted during the desk review and brought to the attention of the hospital associations.

**General Wage Index Comments**

In addition to the points raised above that are specific to issues raised in the Proposed Rule, the FAH also has two comments about current wage index policy generally that are not related specifically to any part of the Proposed Rule.
Countywide reclassifications of hospitals with new provider numbers

Under current wage index policy, a hospital with a new Medicare provider number (whether due to being acquired by another institution or commencing operations as a completely new entity) cannot participate in a reclassification to another wage index area until it has at least one year of data that matches one of the three years of data used by the Medicare Geographic Classification Review Board (“MGCRB”) to reclassify hospitals. In this regard, in cases where a countywide reclassification has been approved by the MGCRB, a hospital with a new provider number is not able to obtain the same reclassified wage index as other facilities in the same area until the first year of the individual hospital’s wage index matches one of the three years data used by the MGCRB and a new three years countywide reclassification is requested by the county's hospitals.

As such, there can be a four year delay in a hospital with a new Medicare number being able to take advantage of a geographic reclassification for wage index purposes. This means that the hospital with a new Medicare number will, for a period of multiple years, have a wage index lower than the hospitals in the same county with which it must compete for skilled labor and, consequently, faces a disadvantage in this regard. The FAH believes that the current policy needs to be changed to allow for a more timely, competitive wage index for hospitals with new Medicare numbers.

Further, the current policy can create a significant disincentive for stable hospitals or systems to acquire other nearby facilities that are in financial distress and in jeopardy of closing. For example, under the current system, if a hospital that was in a county that was reclassified by MGCRB acquired a distressed hospital in another county, it would be considered a “new” provider and therefore not eligible to immediately participate in the reclassification. That facility could then potentially lose millions of dollars by virtue of being classified differently than the other facilities in the same county for wage index purposes, all because it attempted to save a hospital that was at risk of going out of business. The FAH does not imagine CMS intends to perpetuate such inequitable results.

Consistent with the foregoing, the FAH proposes that CMS amend the current regulations concerning geographic reclassifications to ensure that even hospitals that are technically “new” providers by virtue of acquiring another facility can still obtain the benefit of a reclassification decision, so long as data from that hospital was considered as part of the underlying reclassification determination. The FAH believes making this modification to the regulations will prevent anomalous and potentially punitive scenarios like the one described above from arising.

Disproportionate Share Hospitals

IV.D. Proposed FY 2016 Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

FAH appreciates CMS’s engagement of the hospital industry with regard to the calculation methodology that Congress has required to determine uncompensated care payments to disproportionate share hospitals under Section 3133 of the Affordable Care Act of 2010
(“ACA”), codified at 42 U.S.C. § 1395ww(r). In particular we very much appreciate the actions CMS took in the FY 2015 rule-making to correct an inequity that occurred in the FY 2014 rule-making commentary that penalized hospitals that had merged in periods where CMS used data to calculate hospitals payments in Factor 3, as set forth in ACA section 3133. Restoring the correct level of uncompensated care payments to hospitals that have merged, where the surviving hospital has accepted assignment of the provider agreement of the retired provider, affected a small number of hospitals, but many of those are safety net hospitals dependent on such payments.

Our comments below focus on an issue that carries over from concerns we expressed in last year’s comment letter with regard to the Factor 1 calculation and an absence of agency transparency with regard to that calculation. We find this lack of transparency particularly troubling where Congress has generally foreclosed subsequent review, making the adequacy and completeness of notice and comment rule-making that much more important from a Constitutional due process perspective. Additionally, we provide comments below regarding the Factor 2 calculation and alternatives we believe CMS should consider so that it can address changes in the insured population if the Supreme Court’s decision in King v. Burwell, No. 14-114 (U.S. Oral Argument held Mar. 4, 2015), expected in late June or early July of this year, sets aside a portion of the ACA exchange subsidies.

A. Comments Regarding Factor 1 Calculation

We have reviewed the FY 2016 IPPS Proposed Rule: Medicare DSH Supplemental Data File, particularly the spreadsheet titled “FY 2016 NPRM Medicare DSH Estimates” that CMS has made available on its website in support of the proposed rule. We believe that CMS may be understating the Medicaid expansion and the amount of DSH that would be paid in FY 2016 but for ACA section 3133, as it did in FY 2014, which significantly understates the DSH pool that is used to calculate Factor One and ultimately impacts the calculation of the Additional DSH funding pool in Factor Two.

1. Concerns with the “Other” Column of the Factor 1 Calculation

We are concerned that CMS chose to use an “Other” factor of 0.9993 for FY 2014 in its build-up calculation of Factor 1 for FY 2016. 80 Fed. Reg at 24,485. While the details of the “Other” factor in the calculation are not provided by CMS in the proposed rule (a separate problem that causes inadequate notice for comment purposes under the APA), CMS has indicated that one component of “Other” concerns the expansion (or contraction) of the Medicaid population, which has an impact on the calculation of DSH payments. It is particularly surprising that a negative factor was used for FY 2014 in the proposed FY 2016 calculation of Factor 1 for two reasons: First, FY 2014 is the first year of the Medicaid expansion called for under ACA, and given that a significant number of state’s did expand their Medicaid populations in that year, it is counterintuitive that the Medicaid population would have experienced a contraction. As with many other elements impacting Factor 1, it remains unexplained in this proposed rule why the Medicaid expansion does not result in a positive impact on the “Other” column of CMS Factor 1 calculation.
Second, looking back to the FY 2015 IPPS Final Rule’s Factor 1 calculation, CMS used a significantly more positive “Other” column adjustment of 1.0355 for FY 2014, versus a negative adjustment (less than one) of .9993 in this year’s proposed rule. See 79 Fed. Reg. at 50010. Yet nowhere in the proposed rule does CMS explain its change in thinking regarding the impact of the expansion in traditional DSH payments in FY 2014. While we know that ACA Medicaid expansion must affect the traditional DSH calculation for Factor 1 in the “Other” column, CMS provides no information or data regarding the elements of the “Other” column, including the impact of the ACA Medicaid expansion in the proposed rule.11

Subsequent to the issuance in the proposed rule, further inquiry with the agency indicated that to some extent, the “Other” column calculation was impacted by the total “Discharge” calculation determination that discharges in total are falling faster than what was factored into the FY 2015 Final IPPS Rule “Discharge” calculation, but that this is trend information because no actual data yet exists for FY 2014. Those informal discussions also indicate this falling discharge trend was more prevalent at IPPS hospitals than in the total hospital population necessitating a negative impact on the “Other” calculation. We noted in those informal discussions that this was likely caused by the CMS two-midnight policy and was directly contrary to the CMS assumptions underlying the 0.2% reduction in FY 2014 and continuing through this proposed rule, but that the moratorium on enforcement of the two-midnight policy was moderating this trend. In addition, we expect that counter trend information, informing a positive “Other” calculation factor, also includes the expected increase in hospitalizations for the new Medicaid population that would for the first time have access to inpatient services to satisfy pent up demand for those services. We urge CMS to reassess its assumptions about discharges as well as its impact on the “Other” calculation for FY 2014 and later years in the final rule.

Finally, a review of growth factors in traditional DSH payments leading up to ACA indicates that the trend shows continued growth in such payments, 3.27% on average between 2007 and 2013, even without the ACA expansion. We believe the growth rate in DSH payments is actually higher than the current data indicates because the completion factor for the cost reports in HCRIS for 2012 and 2013 is low. See the second table below. Only about half of the 2012 cost reports appears to have adjusted Medicaid days counts present and only approximately 20% of 2013 cost reports contain adjusted Medicaid days data. As CMS has indicated, state Medicaid data is usually only provided well after cost reports are filed, and those cost reports must be adjusted after filing to accommodate the additional information. See 80 Fed. Reg. at 24,487 col. 3 where CMS indicates it is using older cost reports to procure Medicaid days data to ensure completeness of that data.

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11 CMS does indicate that OACT’s estimates are based on the December 2014 update to HCRIS, see 80 Fed. Reg. at 24,484 col.2, but CMS refers providers to the Medicare DSH Supplemental Data File, which on line 4 indicates this version of HCRIS is the March 2014 update. If the DSH Supplemental Data File is the data source that OACT used for purposes of its estimates, which is the March 2014 update, OACT relied upon outdated data. We assume that for purposes of the final rule OACT will recalculate the Factor 1 pool from the most recent version of HCRIS then available.
We tested our thesis that the use of these immature cost reports for FYs 2012 through 2014 from a Medicaid days perspective would generally lead to a lower than appropriate traditional DSH payment determination by reviewing iterations of Medicare cost reports filed for every DSH eligible hospital in the 2552-10 version of HCRIS for FYs 2010 through 2012. A summary of that data is provided in the table immediately below. The data from HCRIS indicates that over time, particularly as cost reports are amended to capture late reports from states on Medicaid days that in fact, Medicaid days used to calculate providers’ traditional DSH payment increase by 1.4% on average for these three years. That figure is likely understated because the FY 2012 data is still immature.
### Summary of Medicaid Days in HCRIS for Cost Report Years Beginning in 2012
Extracted from 12 Quarterly HCRIS updates from December 2012 until March 2015

<table>
<thead>
<tr>
<th>FY</th>
<th>Status March 15</th>
<th>No. Hospitals</th>
<th>March 15 HCRIS</th>
<th>As Filed Avg</th>
<th>Change</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>Amended</td>
<td>68</td>
<td>1,847,190</td>
<td>1,809,794</td>
<td>37,397</td>
<td>2.0%</td>
</tr>
<tr>
<td></td>
<td>Reopened</td>
<td>45</td>
<td>473,424</td>
<td>470,964</td>
<td>2,460</td>
<td>0.5%</td>
</tr>
<tr>
<td></td>
<td>Settled w/o Audit</td>
<td>686</td>
<td>4,753,563</td>
<td>4,705,895</td>
<td>47,669</td>
<td>1.0%</td>
</tr>
<tr>
<td></td>
<td>Settled with Audit</td>
<td>95</td>
<td>1,888,828</td>
<td>1,866,426</td>
<td>22,402</td>
<td>1.2%</td>
</tr>
<tr>
<td>2010 Total</td>
<td></td>
<td>894</td>
<td>8,963,005</td>
<td>8,853,078</td>
<td>109,927</td>
<td>1.2%</td>
</tr>
<tr>
<td>2011</td>
<td>Amended</td>
<td>301</td>
<td>6,794,170</td>
<td>6,546,067</td>
<td>248,103</td>
<td>3.7%</td>
</tr>
<tr>
<td></td>
<td>Reopened</td>
<td>137</td>
<td>893,523</td>
<td>883,001</td>
<td>10,522</td>
<td>1.2%</td>
</tr>
<tr>
<td></td>
<td>Settled w/o Audit</td>
<td>2,155</td>
<td>13,091,142</td>
<td>13,055,631</td>
<td>35,511</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>Settled with Audit</td>
<td>183</td>
<td>3,449,991</td>
<td>3,432,747</td>
<td>17,244</td>
<td>0.5%</td>
</tr>
<tr>
<td>2011 Total</td>
<td></td>
<td>2,776</td>
<td>24,228,826</td>
<td>23,917,446</td>
<td>311,380</td>
<td>1.3%</td>
</tr>
<tr>
<td>2012</td>
<td>Amended</td>
<td>620</td>
<td>9,992,632</td>
<td>9,733,762</td>
<td>258,870</td>
<td>2.6%</td>
</tr>
<tr>
<td></td>
<td>Reopened</td>
<td>35</td>
<td>238,144</td>
<td>233,674</td>
<td>4,470</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>Settled w/o Audit</td>
<td>1,036</td>
<td>6,017,049</td>
<td>6,000,510</td>
<td>16,539</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>Settled with Audit</td>
<td>87</td>
<td>1,245,582</td>
<td>1,235,250</td>
<td>10,332</td>
<td>0.8%</td>
</tr>
<tr>
<td>2012 Total</td>
<td></td>
<td>1,778</td>
<td>17,493,407</td>
<td>17,203,196</td>
<td>290,211</td>
<td>1.7%</td>
</tr>
<tr>
<td>Grand Total</td>
<td></td>
<td>5,448</td>
<td>50,685,238</td>
<td>49,973,721</td>
<td>711,517</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

Cost report amendments to address this data indicate an even larger increase of about 3% on average over the three years we reviewed. This needs to be factored into the calculation of Factor 1 and because of the absence of transparency by the agency in its “Other” calculation it is impossible for the interested public to know whether and how such a calculation was considered.

We next tested the impact of these changes in Medicaid days and other data as cost reports become more mature by reviewing cost reports beginning in FYs 2011 or 2012 to see what happened to traditional DSH payments as the cost reports became more complete. The table below presents a summary of our findings:
Summary of DSH Payments in HCRIS for Cost Report Years Beginning in 2011 or 2012
Extracted from 12 Quarterly HCRIS updates from December 2012 until March 2015

<table>
<thead>
<tr>
<th>Status as of March 15 HCRIS</th>
<th>DSH Payments</th>
<th>DSH on As Filed Cost Report</th>
<th>Change</th>
<th>% Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Reports with Status Changes</td>
<td>March 15 HCRIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amended</td>
<td>5,722,844,120</td>
<td>5,479,511,125</td>
<td>243,332,995</td>
<td>4.4%</td>
</tr>
<tr>
<td>Reopened</td>
<td>330,118,724</td>
<td>327,437,103</td>
<td>2,681,621</td>
<td>0.8%</td>
</tr>
<tr>
<td>Settled w/o Audit</td>
<td>6,205,728,117</td>
<td>6,195,277,480</td>
<td>10,450,637</td>
<td>0.2%</td>
</tr>
<tr>
<td>Settled with Audit</td>
<td>1,433,780,887</td>
<td>1,439,902,252</td>
<td>(6,121,365)</td>
<td>-0.4%</td>
</tr>
<tr>
<td>Total cost reports with Status Changes</td>
<td>13,692,471,848</td>
<td>13,442,127,961</td>
<td>250,343,887</td>
<td>1.9%</td>
</tr>
<tr>
<td>Cost Reports Indicated as Filed in March 2015</td>
<td>9,128,064,668</td>
<td>9,119,249,609</td>
<td>8,815,059</td>
<td>0.1%</td>
</tr>
<tr>
<td>HCRIS</td>
<td>1,860,141,394</td>
<td>1,860,141,394</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>Total All DSH Payments</td>
<td>24,680,677,910</td>
<td>24,421,518,963</td>
<td>259,158,947</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

From the above it is clear that the process of cost report maturation (settling cost reports with or without audit) yields a meaningful increase in both DSH Payments and the underlying Medicaid days used to calculate those payments. Payments increase by 4.4% just from the process of including days late reported by states and on average over the two year period all factors that impact payment yield a 1.1% increase. And that figure derives from inclusion of the period that CMS used as its baseline period, FY 2012, where 47.23% of cost reports still have no reported change and are immature.

It is not logical, without supporting data to the contrary, that in the first year of the ACA Medicaid expansion, with a previously unmet, pent up need for care in the low income population, that Medicaid expansion would lead to fewer hospitals services. In the FY 2016 IPPS Proposed Rule, CMS has offered nothing concrete to indicate what they believe the impact of Medicaid expansion should have on Factor 1. Additionally, CMS has offered no data or explanation upon which the interested public could meaningfully comment regarding how it has handled the immature nature of the cost reports it is using in FY 2012, its baseline for these calculations.

12 We did not include a calculation of FY 2010 cost report data for DSH payment purposes because of several aberrational aspects with that year’s data. First, the FY 2010 cost reports were impacted by a late release of relevant SSI data following their filing. Most of these cost reports were filed with SSI information 3 years older than normal. Second, only a third of the FY 2010 cost reports were filed using CMS Form 2552-10 and we could not accurately merge data from the two different cost report forms for that year.
2. Concerns with the Discharge Count

Much like our concerns with the change in the “Other” component of the Factor 1 calculation for FY 2014, CMS has reduced the number of Medicare discharges in its calculation of traditional DSH payments between the FY 2015 IPPS Final Rule, a factor of .9855, and this year’s proposed rule, a factor of .9595. CMS indicates that the discharges for FY 2014 are derived from preliminary data from 2015. We certainly understand that such data may change as it becomes more complete over time, but here CMS does not provide any data or assumptions that would allow the industry to comment on the accuracy of its calculation of discharges, because it does not disclose how such discharge data is adjusted by a completeness factor. And because once this Rule becomes final CMS is unlikely to further alter these calculations, its failure to provide this data prevents meaningful comment that could ensure a correct calculation of this important factor. This is concerning because as the data for each year becomes more complete, patient days usually are added, not deleted. CMS data for what has happened with its FY 2013 calculation is typical of this. The discharge factor increased somewhat significantly between the FY 2015 IPPS Final Rule and this proposed rule.

B. Comments Regarding Factor 2 Calculation

In Factor 2, the Secretary measures the difference between the percentage of individuals under the age of 65:

(I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

(II) who are uninsured in the most recent period for which data is available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017. [42 U.S.C. § 1395ww(r)(1)(B)]

The Secretary has already determined that the first part of the calculation, the percentage of those who are uninsured in 2013, is fixed and based on a report from the Director of CBO shortly before the passage of ACA. For the second part of the calculation, the percentage of uninsured in the most recent period, the Secretary has determined that she will use the most recent update from the CBO about the current percentage of the uninsured population, but the percentage itself will be calculated by the Secretary and will be subject to some adjustment. For example, in the FY 2014 IPPS Final Rule, the Secretary adjusted the CBO estimate to account for the difference between the calendar year and applicable federal fiscal year. See 78 Fed. Reg. at 50633.

Our concern this year is that the Supreme Court has now heard a case, King v. Burwell noted above, challenging the legality of the insurance exchange subsidies in states that do not offer state-operated exchanges, which represents a majority of states. The Robert Wood Johnson
Foundation ("RWJF"), in conjunction with the Urban Institute, issued a study in January 2015, Linda J. Blumberg, Matthew Buettgens, and John Holahan, *The Implications of a Supreme Court Finding for the Plaintiff in King v. Burwell: 8.2 Million More Uninsured and 35% Higher Premiums*, that estimates that if the Supreme Court sets aside the subsidies in states without state-operated exchanges, approximately 8.2 million more Americans would be uninsured in CY 2016, resulting in a national uninsured rate of 15.1 percent. A more recent May 2015 study by the same authors, *The Combined Effect of Not Expanding Medicaid and Losing Marketplace Assistance*, calculates the impact of such a decision on the 20 states that did not expand Medicaid under ACA, estimating an increase in the uninsured population of 9.8 million people in those 20 states in CY 2016. Of this 9.8 million uninsured increase, 4.3 million come from Texas and Florida alone. The uninsured rate would increase to 18.3 percent in those states in CY 2016. The actual increase in the uninsured population could be larger than this estimate when it includes the impact of such a Supreme Court decision on states that did expand Medicaid, but do not have state-operated exchanges. Needless to say, either of these estimates represents a significant increase in the uninsured population not reflected in the most recent CBO estimate for the current period. Even assuming, *arguendo*, that the increase in the uninsured rate would not occur until CY 2016, this increase would significantly alter the FY 2016 Proposed Uncompensated Care Amount in Factor 2. The table below walks through the Factor 2 analysis, comparing the Factor 2 calculation using CBO’s March 2015 projections with the Factor 2 calculation using RWJF’s more modest uninsured projection for CY 2016 (i.e., the January 2015 national estimate of 15.1 percent).

<table>
<thead>
<tr>
<th>Proposed Factor 2 for FY 2016</th>
<th>Factor 2 Projection After Victory for Petitioner in <em>King v. Burwell</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>CY 2015 rate of insurance coverage (March 2015 CBO estimate): 87 percent</td>
<td>CY 2015 rate of insurance coverage (March 2015 CBO estimate): 87 percent</td>
</tr>
<tr>
<td>CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent</td>
<td>CY 2016 rate of insurance coverage (RWJF estimate): 85 percent</td>
</tr>
<tr>
<td>FY 2016 rate of insurance coverage: (87 percent x .25) + (89 percent x .75) = 88.5 percent</td>
<td>FY 2016 rate of insurance coverage: (87 percent x .25) + (85 percent x .75) = 85.5 percent</td>
</tr>
<tr>
<td>Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent</td>
<td>Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent</td>
</tr>
<tr>
<td>Percent of individuals without insurance for FY 2016 (weighted average): 11.5 percent</td>
<td>Percent of individuals without insurance for FY 2016 (weighted average): 14.5 percent</td>
</tr>
<tr>
<td>1-((0.115 - 0.18)/0.18) = 1 - 0.3611 = 0.6389 (63.89 percent) - .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.6369 or 63.69 percent</td>
<td>1-((0.145 - 0.18)/0.18) = 1 - 0.1944 = 0.8056 (80.56 percent) - .002 (0.2 percentage points for FY 2016 under section 1886(r)(2)(B)(i) of the Act) = 0.8036 or 80.36 percent</td>
</tr>
</tbody>
</table>
The above table demonstrates the potential dollar impact of the updated insurance rate on the total available uncompensated care amount for FY 2016, namely a difference of nearly $2 billion to hospitals. America’s safety-net hospitals will desperately need these uncompensated care payments to offset the significant increase in uncompensated care provided to the many uninsured patients walking through their doors.

Specifically, we suggest that CMS consider the decision expected in the coming weeks from the Supreme Court of the United States and the decision’s potentially significant impact on the FY 2016 insurance rate used to develop the Factor 2 calculation. In light of the impending decision, FAH requests that the Secretary take one of two courses of action. First, given that the Secretary already has taken a role in the Factor 2 calculation by converting the CBO’s calendar year calculation to a Federal Fiscal Year calculation, the Secretary has determined that it need not accept the CBO’s most recent estimate of the insured population as rote and nothing in the legislation mandates simply taking the CBO estimate as the applicable percentage. Indeed, the legislation requires the Secretary to calculate the percentage “based” on the CBO estimate. If the Secretary agrees that she can use the latest CBO estimate that does not take into account a King v. Burwell decision and calculate from that CBO estimate the percentage of uninsured as a consequence of that decision, that could be accomplished before the final rule is published, given that she would likely have at least 20 days from the Supreme Court’s decision before finalizing the rule. Alternatively, if the Secretary believes a longer period of time is necessary to calculate such percentage taking into account the Supreme Court’s decision, the Secretary could issue that portion of the rule concerning the uncompensated care payment calculation in interim final form, and finalize the calculation before October 1 of this year, the effective date of the rule. Either approach would work to ensure an accurate payment based on the real uninsured population.

Second, if the Secretary does not agree that she can calculate the impact of the Supreme Court’s decision on the CBO estimate, but must wait for the CBO to perform its own estimate, we note that CBO quickly responded to the last Supreme Court decision on the Medicaid expansion (i.e., CBO released new estimates on July 24, 2012, to account for the Supreme Court’s June 28, 2012 decision in National Federation of Independent Business v. Sebelius). However, the Secretary has no authority to compel CBO to issue a revised estimate by a date certain. So once again, under this option, we also suggest the Secretary plan to issue this part of the rule in interim final form to give the CBO time to perform such estimate and allow the Secretary to calculate an uninsured percentage that will more closely reflect the reality of the then current landscape for the health insurance population.
Nothing we suggest above affects the Factor 3 calculation. Those individual hospital factors will remain the same, although they will be applied to a different and potentially larger dollar pool.

We certainly hope that the Secretary will carefully consider our concern above. There will be a considerable shuffling of the health care system if the Supreme Court sets aside the exchange subsidies in *King v. Burwell*, but the calculation of uncompensated care payments does not have to be part of such dislocation of health care resources. Instead, the timely consideration of the Supreme Court’s decision by the Secretary in the context of this part of the rule can be of great assistance to a system that will struggle under such a decision.

C. Factor 3 Comments - We Agree With CMS that Worksheet S-10 Data as the Basis for Apportioning Payment to DSH Eligible Hospitals Under Factor 3 Would Yield Arbitrary Results.

1. The Worksheet S-10 Data in the March 31, 2013 and 2014 HCRIS Data Files Contains Significant Anomalous Data

CMS correctly concluded in last year’s final rule that available Worksheet S-10 (hereinafter “S-10”) data is too unreliable to use as a basis to allocate many billions of dollars in hospital payments and has reiterated those concerns in the FY 2015 proposed rule. 79 Fed. Reg. at 28100. When we commented on last year’s proposed rule we noted the following problems from S-10 reported in the March 31, 2013 HCRIS data base.

- 242 or 9% of the 2,666 DSH hospitals did not have any bad debt expense indicated on S-10 on line 26. 226 of these 242 hospitals (93%) had Medicare Bad Debts indicated on line 27. It is difficult to imagine that some hospitals did not have any bad debt expense or that they only had Medicare bad debt.

- 6 of the 2,666 hospitals had more charges indicated on S-10 than the gross charges indicated on Worksheet C. In total these 6 hospitals had $9,913,024,894 in charges on S-10 compared with $6,868,691,477 on worksheet C of the cost reports. The charges on S-10 were developed by adding lines 6, 10, 14, 20 and 26 together. Column 3 was utilized for line 20. One hospital had $1,801,748,773 in charges on S-10 versus $103,918,204 on Worksheet C.

- 5 hospitals had a ratio of cost to charges (CCR) indicated on S-10 equal to 100%. In reviewing these hospitals’ Worksheet G, their CCR should be under 1.00. These hospitals are all inclusive rate facilities in New York. Such CCRs would appear to inflate these hospitals uncompensated care cost. CMS should review these hospitals and correct the CCRs.

- 97 hospitals have a CCR of greater than 60% including 2 of the 6 hospitals where the S-10 charges exceed Worksheet C. The national average CCR is .343. CMS should review all hospitals with a high CCR to insure it is correct.
None of the 2,633 hospitals that received Medicare DSH payments based on their latest 2552-10 cost report have an audited S-10 in HCRIS.

Those problems continued to persist in the March 31, 2014 HCRIS data base for all Form 2552-10 cost reports, which includes the current S-10:

- Within the data base, only 69 cost reports from 6935 cost reports with DSH payments have been settled with audit and there is no evidence of adjustments to S-10 data, perhaps not surprising given FAH member experience that the electronic health records audits of payment data began in late calendar year 2013;

- Within that same data base, 569 cost reports are showing no bad debt on S-10;

- For 23 cost reports, charges on S-10 exceed total hospital charges on Worksheet C for the entire patient population, in 19 instances by more than a factor of 10, and in the aggregate for these hospitals S-10 charges exceeded Worksheet C charges by $25,047,313,021;

- 50 S-10s show a cost to charge ratio greater than or equal to 100% and 10 of those show a cost to charge ratio of exactly 100%;

- 308 S-10s show a cost to charge ratio greater than 60%, where the average cost to charge ratio is 33.85 percent;

Even the most current version of HCRIS, the March 31, 2015 HCRIS database for all Form 2552-10 cost reports, which includes the current S-10, supports the notion that S-10 cannot be used to determine uncompensated care costs and allocate the Factor 2 pool of uncompensated care funds:

- Within the data base, only 355 cost reports from 9892 cost reports with DSH payments have been settled with audit;

- Within that same data base, 717 cost reports are showing no bad debt on S-10;

- For 30 cost reports, charges on S-10 exceed total hospital charges on Worksheet C for the entire patient population, in 10 instances by more than a factor of 10, and in the aggregate for these hospitals S-10 charges exceeded Worksheet C charges by $29,587,792,079;

- 64 S-10s show a cost to charge ratio greater than or equal to 100% and 24 of those show a cost to charge ratio of exactly 100%;

- 427 S-10s show a cost to charge ratio greater than 60%, where the average cost to charge ratio is 33.78 percent.

The data suggests little improvement in the accuracy of hospitals’ reporting of data in S-10, with more hospitals continuing to report aberrant data or missing essential data for a fair implementation of S-10 as the basis for payment from the UC DSH pool.
2. **We Agree with CMS that Considerable Work Needs to be Done to Clarify S-10 Instructions and Audit that Data Before it is Used to Apportion DSH Payments Under Factor Three**

The Secretary acknowledges that:

We believe this methodology would give hospitals more time to learn how to submit accurate and consistent data through Worksheet S–10, as well as give CMS more time to continue to work with the hospital community and others to develop the appropriate clarifications and revisions to Worksheet S–10 to ensure standardized and consistent reporting of all data elements. [80 Fed. Reg. at 24,487 col. 1].

Before the S-10 data can achieve the level of reliability the Secretary notes above, the instructions associated with its preparation need to be clarified to allow the consistent reporting of the relevant data across all affected hospitals. As we see such a timeline, if S-10 instructions are not amended until the middle of FY 2015, cost reports using such instructions for the first time will not be filed until sometime beginning in FY 2016. The first relevant audits will not occur until 2017 at the earliest and hospitals will not have the benefit of such audits to report S-10 data that may be usable for this purpose until FY 2018. Thus, moving quickly to satisfy the Secretary’s criteria for the use of this data is imperative. CMS should endeavor to revise S-10 to capture relevant data and revise instructions so that such data can be reported consistently by all hospitals and audited. We offer the below comments to assist in the revision of S-10 and its instructions.

a. **Definitional Issues with S-10**

The definition of “uncompensated care” and its constituent components “charity care” and “bad debt” are not sufficiently defined to support consistent reporting by hospitals. The following are examples of areas within the S-10 instructions that require clarification.

**Uninsured Versus Charity** - The definition of “[u]ncompensated care does not include … discounts given to patients.” PRM-II § 4012 Definitions. While many hospitals “income test” patients before providing discounted care, some provide such discounts for any uninsured patient, and some states, e.g., Tennessee, mandate such discounts and do not allow income inquiries. If income testing to qualify a discount as charity care is mandated, this might preclude Tennessee hospitals, or those in similarly situated states, from ever recording charity care. The instructions for line 20 of the worksheet further suggest income testing is required: “Do not include charges for either uninsured patients given discounts without meeting the hospital's charity care criteria or patients given courtesy discounts.” CMS must develop a definition that treats all such hospitals fairly for purposes of the cost of uncompensated care comparison. Section 3133 of ACA references the uncompensated care costs of the uninsured. It does not reference charity care.

**Timing of Charity Determination** – Line 20 instructions require the reporting of charges for charity care in the period care is provided. A cost report must be filed within 150 days of the
period-end. Charity care determinations frequently lag the provision of care pending the production by the patient of qualifying income. Some charity care will be missed as a consequence of this definition. Instead, CMS could revise the timing of the reporting of charity care charges to the period when the eligibility determination is made, rather than for the period of service. Such a timing determination is more likely to capture the cost of all such care.

**Indigent Care Program Versus Charity** - CMS indicates “[c]harity care results from a hospital’s policy to provide all or a portion of services free of charge to patients who meet certain financial criteria.” Id. The instruction for line 20 further provides: “Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program … can be included, if such inclusion is specified in the hospital’s charity care policy and the patient meets the hospital's charity care criteria.” We believe government providers are misreporting data related to charity care under the above definition by including all charges for their indigent care/general relief patient populations in the definition. These programs are not uncompensated, but are paid through local and state tax assessments. CMS needs to clarify that patient charges cannot be included in the cost of charity care unless, as provided above, the related services are not covered by an indigent care program.

**Medicaid Non-Covered Charges** – S-10 line 20 instructions specify that “Charges for non-covered services provided to patients eligible for Medicaid or other indigent care program (including charges for days exceeding a length of stay limit) can be included, if such inclusion is specified in the hospital's charity care policy and the patient meets the hospital's charity care criteria.” Many hospitals non-covered charges for Medicaid beneficiaries simply fall into a deduction from revenue category that summarizes into the Medicaid financial class, not in the charity GL financial accounts. Most hospitals’ charity care policies do not specifically deem non-covered Medicaid charges as charity care for financial statement purposes, even though such patients financially qualify as such. The form instructions do have a separate line for Medicaid charges in excess of day limits for Medicaid coverage, but not simply non-covered charges separate and apart from the day limitation. That line item should aggregate both items, and there should be no separate requirement that Medicaid beneficiaries be mentioned in the charity policy.

**Timing of Bad Debt Determination** - Bad debts reflected on the S-10 do allow the reporting of total hospital bad debts on a full accrual basis since the form instructions for line 26 clearly state: “bad debts (bad debt expense) written off or expected to be written off on balances owed by patients delivered during the cost reporting period.” CMS needs to clearly state they mean fully allowed for bad debt expense as reflected on a hospital’s financial statement. Also, the reference in the Non-Medicare bad debt definition to the line 25 instruction is incorrect and should refer to the line 26 instruction.

Using Generally Accepted Accounting Principles to Report Bad Debt and Charity Care on S-10 Consistent with Hospital Financial Statement Reporting - We are concerned that timing differences between when services are provided and charity and bad debt determinations are made will vary so significantly among providers under current S-10 instructions used to report such data that hospital to hospital comparisons are almost meaningless. To cure these timing differences, we strongly recommend that S-10 instructions be amended to require that hospitals
report on that form the same bad debt and charity care amounts that they report for purposes of GAAP on their financial statements.

b. **Consistency in Calculating Uncompensated Care Costs**

The payment system that Section 3133 imposes for Additional DSH requires absolute consistency in calculation among hospitals to insure that funds are equitably distributed. We are concerned that the S-10 instructions are insufficiently specific to insure that hospitals consistently reduce charges to costs, particularly with regard to calculating bad debt costs. Set forth are a couple of examples to show how results will differ in calculating costs depending on the view of what the charge actually is in a given instance.

In this first example, a hospital has a PPO arrangement with an insurer where it has agreed to accept a per diem for patient services and the beneficiary pays a flat copayment amount of $200 for inpatient care. In this example gross charges are $100,000, the hospital accepts as payment $100,000, the hospital accepts as payment from the insurance plan $50,000 for a ten-day stay, and the hospital is unable to collect the $200 copayment from the beneficiary and it has a cost to charge ratio of 0.2. What is the cost of the unpaid copayment? If gross charges are allocated between the insurer’s payment and the beneficiary’s liability, the charge applicable to the copayment is $400 and after application of the cost to charge ratio the cost is $80. But the hospital never expected to collect more than the $200 from the beneficiary so should a hospital be allowed to gross-up that amount to $400 before application of the cost to charge ratio? If the $200 is not grossed-up, the cost of that portion of the service is $40, not $80, or half of the reported amount. We believe the simplest and most consistent approach to this is to make clear in the instructions that the hospital cost to charge ratio be applied to the uncollected patient liability, the amount the hospital agreed to accept as payment in full.

In the second example, the insurer pays 80% of charges, and the beneficiary is responsible for 20% of charges. Gross charges are $100,000 and the cost to charge ratio is 0.2. The beneficiary is liable for the $20,000 copayment, but does not pay the patient liability. The cost of the bad debt in this instance is $4,000 because the beneficiary liability is full charges. However, if the insurer’s discount extended to the beneficiary copayment, the cost of the bad debt should be lower by a corresponding amount.

We believe that hospitals address each of these examples inconsistently when reporting information on S-10, and that it is critical to fair apportionment of payments that such data be reported consistently.

**Hospital Readmissions**

**IV. E. 4. Proposed Refinement of Hospital 30-Day, All Cause Risk-Standardized Readmission Rate Following Pneumonia Hospitalization Measure Cohort for FY 2017 and subsequent years**

The FAH opposes the CMS proposal to expand the cohort of patients included in the pneumonia readmission measure at this time. The proposed measure expansion would
add patients with a principal diagnosis of aspirational pneumonia and also those with a discharge diagnosis of sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. We agree that this is a major change properly considered in notice and comment rulemaking. CMS has estimated that the proposal would increase the size of the patient cohort by an estimated 65 percent (more than 634,000 patients). The expansion of the patient cohort is more than a refinement. The expansion of the cohort essentially makes this a new measure that the FAH believes should be thoroughly vetted, tested and endorsed by the National Quality Forum ("NQF"). In addition, the revision does not include tools for stratification and adjustment for socio-economic factors, an addition the FAH supports for all readmission measures.

The Measure Applications Partnership conditionally supported a revised version of the measure for use in HRRP pending review of the updated measure by the relevant NQF Standing Committee, and stressed the importance of that review. The MAP also noted that this measure should be considered for sociodemographic status (SDS) adjustment in the upcoming NQF trial period, reviewed for the empirical and conceptual relationship between SDS factors and pneumonia readmissions, and endorsed with appropriate SDS adjustment as determined by NQF standing committees.

Finally, once the measure is revised, tested and endorsed, hospitals need at least one year of reporting this measure publicly and assessing the impact of the new patient cohort before it is added to the HRRP payment penalty program.

From a clinical perspective, the proposed changes to the pneumonia measure raise particular concerns. Because sepsis is a complex disease and one with rapidly evolving treatment protocols, it is unclear whether inclusion of all these patients in the pneumonia readmission measure at this point will increase our clinical understanding of preventable pneumonia readmissions. Aspirational pneumonia is often the result of an underlying medical condition, and repeat episodes may not be easily avoided. Adding the large volume of patients with these conditions to the measure will make it less homogeneous and therefore more difficult to interpret hospital performance. In addition, the added specificity in ICD-10 coding creates potential for changes in the pneumonia measure and other measures when implementation begins this fall. For all these reasons the NQF review and endorsement process is especially important with respect to the proposed changes to the pneumonia readmission (and mortality) measure, and the FAH urges CMS not to adopt the proposed revised pneumonia measure unless and until a review is completed and the measure is endorsed by NQF. The FAH also urges CMS to make public any modeling it has completed on measures specified in ICD-10.

The FAH members have a long-standing belief that additional risk adjustment should be used to address socio-economic factors, in particular for readmissions and other outcome measures, and urge CMS to submit this proposed revised pneumonia measure and all the readmissions measures to the trial period assessment process approved by the NQF Board in July 2014. Under the two-step approach recommended by an NQF expert panel, sociodemographic factors are added to the risk adjustment models used for “accountability purposes,” (such as the HRRP) while stratifying on sociodemographic factors for the purposes of identifying and reducing quality disparities. We believe sociodemographic adjustment and stratification are
important tools for accurately assessing health care provider performance for public reporting and accountability programs, particularly with respect to outcomes measurement. Most importantly, the FAH believes that risk adjustment for sociodemographic factors will avoid the unintended consequences that can result without such adjustment when providers serving vulnerable populations are subject to payment penalties. The application of the adjustment should not result in additional losses for any hospital.

The importance of SDS in understanding hospital readmissions was underscored by a recent study which found that nearly 60 percent of the variation in national hospital readmission rates was explained by the county the hospital is located in rather than hospital characteristics. Local factors such as income, employment levels and nursing home quality were the major factors underlying county-level variation.13

Finally, the FAH believes that frequency of reporting on readmissions performance and other claims-based measures should be given priority over expanding the measures. Rather than devoting limited resources to expanding measures, CMS should calculate and report to hospitals performance on the existing measures more frequently. The current annual calculation and release of data does not facilitate the effective measure use for purposes of continuous quality improvement, a critical tool if the readmission reduction program is to be a quality program and not simply a tool for administering payment penalties. While national improvement in readmission rates is occurring, the progress may be further enhanced by more frequent performance reporting. In addition, hospitals do not have access to all the CMS claims data used in the formula which also hampers their ability to replicate data and take appropriate quality improvement actions. The FAH strongly recommends that CMS provide more frequent performance data to assist hospitals in their continuous work on improvement. Routine quarterly reports, even if they are a rolling multiyear measure, would be a significant improvement over the annual-only release of this information. Even semi-annual reports would be an improvement and offer hospitals greater opportunity to develop specific interventions when a problem is identified.


The FAH supports adding an extraordinary circumstances exception policy to the HRRP, and asks that in the future, exceptions be considered more broadly. By building on the exceptions process already in place for the quality reporting and value-based purchasing programs, the proposal would allow CMS to provide relief to hospitals experiencing extraordinary circumstances that prevent the timely submission of claims. With respect to the HRRP, however, we believe the exception process should also recognize situations in which a hospital in an area experiencing a natural disaster or other extraordinary circumstance would be challenged to avoid readmissions that would otherwise be preventable. For example, circumstances outside the hospital’s control may disrupt community services and hospital programs needed to continue readmission prevention efforts, which may result in higher readmission rates. It would be unfair to penalize a

hospital in this circumstance, and the proposed exceptions process should be modified to recognize these situations.

Value-Based Purchasing

IV. F. 2. Removal, Updating, and Addition of Quality Measures for FY 2018

c. Proposed New HCAHPS measure. A proposed addition to the HVBP program beginning in FY 2019 is the NQF-endorsed, 3-part Care Transition measure, which was incorporated into Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) reporting effective with the FY 2015 IQR payment determination. Hospitals began submitting data on this new HCAHPS component to CMS in January 2013, and public reporting of the measure on Hospital Compare began in December 2014. CMS proposes addition of this new HCAHPS dimension to the HVBP without any discussion of hospital performance during the first year of implementation of this component.

While the FAH believes that patient experience is a key aspect of measuring quality of care, we have ongoing concerns about how the current measure is administered, and once again urge CMS to undertake a top-to-bottom review of the entire HCAHPS process. The FAH does not oppose the addition of the three care transition questions; however, adding measures raises concerns about the overall tool. Even before the three care transition questions were added, our members found that the HCAHPS survey is lengthy and can be burdensome on respondents, especially when administered orally to elderly patients. As the FAH has discussed previously with CMS, the oral script required to administer the HCAHPS survey is cumbersome and confusing to elderly patients.

d. Clinical Care – Process Subdomain. The FAH opposes removal of the entire Clinical Care-Process subdomain from the HVBP program. We understand that the measure Influenza Immunization has become topped out, and that the measure AMI-7a “Fibrolynic Therapy Received Within 30 Minutes of Hospital Arrival,” is infrequently reported. Given the previous removal of a number of topped out clinical process measures (which the FAH did not support), we do not object to these proposed removals, or to the proposed shift of the measure “Elective Delivery Prior to 39 Weeks Gestation” to the Safety domain.

However, we believe that clinical process of care measures can play a vital role in quality improvement and that the Clinical Care – Process subdomain, even if weighted at zero for a year or more, should remain a component of the HVBP program. CMS should seek to repopulate this domain with appropriate measures assessing new medical conditions not previously evaluated. In particular, we continue to believe that where process of care can be linked to patient outcomes, measurement of those procedures as well as outcomes is appropriate for quality improvement purposes and for pay-for-performance programs like the HVBP program.

Important topic areas for which process-related measures could be developed, initially for the quality reporting and eventually for the HVBP program, include blood use and blood administration, adverse drug event, and measures (not limited to surgical care) designed to
ensure that broad spectrum antibiotics are only used when other options are not clinically appropriate. The recent White House Forum on Antibiotic Stewardship and the National Action Plan for Combating Antibiotic-Resistant Bacteria include plans for quality measures on antibiotic prescribing, and the FAH believes that appropriate hospital quality measures should be part of this effort.

Finally, to the extent that chart-abstracted process of care measures are being replaced by parallel electronically reported versions, the electronic clinical quality measures (eCQM) should not be used for the HVBP program until all hospitals are reporting the same measures electronically and an appropriate data validation process is in place. Several FAH members have found significant differences when comparing the results of their manually abstracted chart measures to their eCQM measures. Until greater eCQM consistency is achieved across all vendors, eCQMs should not be used in the VBP program.

IV. F. 3. Measures for the FY 2019 and FY 2021 Hospital VBP Program Years

a. Expansion of CLABSI and CAUTI locations. CMS indicates its intention to propose application of the expanded version of the Central Line Blood Stream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures to the HVBP program beginning in FY 2019, and the FAH supports this approach. Reporting of these National Healthcare Safety Network (NHSN) measures for adult and pediatric medical and surgical wards as well as intensive care units (ICUs) began in January 2015. FY 2019 is the first year that would permit use of baseline and performance periods both based on the expanded measures, and is therefore the appropriate time to shift to the broader measure. The FAH also notes the benefits of the Centers for Disease Control and Prevention’s decision to update the standard population data used to calculate predicted infections for all NHSN measures, and to consistently use 2015 data for this purpose across all measures.

If CMS proceeds with this proposal, it is likely that hospital scores will look different from one year to the next. Including a broader cohort and rebasing the measure could produce different results and cause inexperienced users of the data to make assumptions about quality that may be misunderstood. Therefore, clear messaging describing the differences between one year’s data and the next should be provided on Hospital Compare and in any transmission of the data for research purposes. Even though re-basing the measures is appropriate, without clear guidance from CMS and CDC, longitudinal studies comparing the measures results prior to 2015 with results post 2015 will be more difficult and could cause researchers to draw inaccurate conclusions without clear guidance from CMS and CDC.

b. COPD Mortality Measure for FY 2021. CMS proposes to add the measure “Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate following COPD Hospitalization” (NQF #1893) beginning with FY 2021 payment. This measure was posted on the Hospital Compare website for the first time in July 2014, and hospitals do not yet have much experience with it. The FAH again urges CMS to make performance data on this and all claims-based measures available at least quarterly rather than only once a year. Annual data is insufficient to provide actionable information; hospitals need timely feedback in order to know whether the targeted quality improvement activities in which they are engaged have been successful. With respect to
this measure in particular, the FAH believes that COPD mortality is a difficult measure for hospitals to address because mortality is high for patients with this chronic condition. CMS should consider monitoring to be sure that measurement of COPD mortality does not result in some hospitals discouraging admission of certain patients.

IV. F. 4. Possible Future Measure Topics

The FAH does not support the direction suggested in the proposed rule, which would expand the efficiency domain by including a number of condition-specific measures of Medicare spending per beneficiary. In general, the FAH continues to believe that this type of Medicare spending measure is not suited for inclusion in the HVBP program. Hospitals have little ability to affect spending during the defined episode (generally three days prior to admission and 30 days post-discharge) with the exception of addressing preventable readmissions, and readmissions are measured independently for the quality reporting program and the HRRP. We are opposed in particular to inclusion of condition-specific Medicare spending measures for which there are no associated measures of patient outcome or other quality of care indicators in the HVBP program. This is the case for four of the conditions discussed: kidney/urinary tract infection, cellulitis, gastrointestinal hemorrhage, and lumbar spine fusion/refusion.

Performance on the type of Medicare spending measures being considered is largely determined by factors beyond a hospital’s control, such as the quality of care provided by a post-acute care provider (skilled nursing facility or home health agency), physician/practitioner follow-up, patient compliance, and community services. For these reasons, the FAH believes that Medicare spending per beneficiary is a more appropriate measure for assessing performance of Accountable Care Organizations or similar integrated provider systems.

Finally, the existing total MSPB measure as well as the condition-specific spending per episode of care measures identified as potential future HVBP measures may have unintended consequences. Specifically, emphasis on these measures may create an incentive to discharge patients to the lowest-cost setting, which may not be the most appropriate care setting to meet the patient’s needs. CMS should seek to develop efficiency measures that evaluate and properly balance both cost and quality, and appropriate post-discharge quality safeguards should be in place.

As noted earlier (section IV.F.2), we believe that CMS should continue to seek appropriate clinical process measures for future addition to the IQR and HVBP programs. In particular, measures of appropriate antibiotic use should be considered.

IV. F. 7. Proposed Performance Standards for the VBP Program

The FAH supports the proposal to adjust the scoring of the HCAHPS measure to reflect the addition of a ninth dimension. Each of the nine dimension scores would be multiplied by 8/9 so that these nine dimensions would continue to contribute up to 80 points toward the HCAHPS score, and the consistency score would continue to total up to 20 points.
IV. F. 8. Proposed Domain Weighting and Scoring Methodology

a. Domain weighting. CMS proposes equal weighting of the four HVBP program measure domains for FY 2018 payment: 25 percent each for safety, clinical care outcomes, patient experience, and cost efficiency. As noted earlier, we recommend that CMS retain the clinical care process domain at a weight of zero and work to repopulate this domain with appropriate process of care measures for future years when the domain weight could be adjusted.

The FAH continues to have concerns that the efficiency domain is too heavily weighted in the total score. To some degree, performance on this measure is correlated with readmissions and overlaps with the readmissions reduction program. And although hospitals continue to work to improve care coordination care transitions, this measure largely reflects factors beyond a hospital’s ultimate control, such as the quality of care provided by a post-acute care provider (skilled nursing facility or home health agency), physician/practitioner follow-up, patient compliance and community services. We remain concerned that the Medicare spending per beneficiary measure may encourage hospitals to avoid taking high-risk patients or to sacrifice quality of care following discharge by placing patients in a lower-cost post-acute care setting. Heavily weighting this measure heightens the importance of carefully and completely measuring the quality of care and identifying any changes.

The shift to the ICD-10-CM/PCS coding begins in a very few months, and the FAH urges CMS to use the final rule and other communication avenues to report to hospitals on the status of its efforts to assess the impact of the coding system change on program measures. As CMS has noted, the shift to ICD-10 could have a substantial effect on some measures. The FAH is particularly concerned about the possibility that it may not be possible to calculate reliable and valid improvement scores for some measures because the effects of the coding system changes are too great. The strength of the HVBP program is its measurement of both achievement and improvement in quality performance. The FAH is willing to work with CMS in understanding and mitigating the effects of the shift to ICD-10-CM/PCS on HVBP program.

Hospital-Acquired Condition Reduction Program

IV. G. 4. Implementation of the HAC Program in FY 2016

The FAH supports hospitals in their work to provide the safest care possible for patients. However, the FAH continues to have concerns about the HAC payment reduction program. Its simplistic statutory design inevitably leads to some hospitals experiencing a one percent across-the-board payment reduction even though the hospital’s performance is only marginally different from unaffected hospitals. Moreover, all the HAC measures are duplicated in the HVBP program, which more appropriately rewards and penalizes hospitals on a sliding scale based on quality improvement as well as attainment of certain benchmarks. It would be useful for the CMS impact analysis of this program to include information on the distribution of hospital HAC program scores, and in particular, the extent to which small differences in scores are found above and below the penalty threshold.
CMS notes that it intends to work with CDC to determine whether the Adjusted Ranking Metric, or ARM alternative to the Standardized Infection Ratio (SIR) is appropriate for use in the HAC Reduction Program, and if so it will propose a change through notice and comment rulemaking. The FAH views the SIR as a reasonable and understandable methodology, and encourages CMS to be cautious in proposing a fundamental change in how hospital performance is scored for these measures. In particular, it is difficult for hospitals with zero events for a measure to understand why they might receive a score other than zero for that measure.

IV. G. 5. Proposed Changes for FY 2017

b. Calculation of Domain 2 score. CMS proposes that beginning in FY 2017, a hospital that does not submit data for a Domain 2 measure, and does not have a waiver to do so, would receive a maximum score of 10 for that measure and that score would be averaged with the score(s) on other measures. (Currently, if a hospital reports data on one but not all Domain 2 measures, its score will be based solely on the measure(s) reported, and it will not be assigned a maximum score of 10 for the non-reported data.) The FAH supports this proposal.

c. Domain Weights. The FAH recommends the total removal of the Agency for Healthcare Research and Quality (AHRQ) composite patient safety indicator measure (PSI-90) measure from the HAC program. However, if CMS decides to keep PSI-90, the FAH supports the CMS proposed reduction in the weight given to 15 percent beginning in FY 2017 as a positive step toward removal. As the FAH has noted in earlier comment opportunities, we believe this annually-reported claims-based measure lacks actionable information and should be replaced in the future by measures that better support improvements in patient safety. Additional concerns about the structure of this measure were well expressed recently in the *Journal of the American Medical Association*14:

> “As evidenced by a lack of continued maintenance endorsement from the National Quality Forum in 2014, numerous problems exist with the current PSI-90 composite measure: (1) flawed component measures; (2) clinical areas targeted; (3) accuracy of adverse events identified; (4) adequacy of the risk adjustment; and (5) formulation of the composite measure. These flaws may incorrectly identify problem areas for hospitals to address, unfairly penalize hospitals financially, and adversely influence clinician engagement in quality improvement.”

While we understand that PSI-90 continues to undergo NQF review during which additional component measures may be added and component weights adjusted, these changes would not address our fundamental concern about the lack of actionable information it provides. Unfortunately, we recognize that the NHSN measures that comprise the HAC Reduction Program Domain 2 for FY 2016 and 2017 are not applicable to some hospitals, and in these cases the PSI-90 measure provides the total HAC program score. For the future, when broadly applicable NHSN measures are available, CMS should eliminate PSI-90 from the program entirely.

IV. G. 6. Proposed Measure Refinements for FY 2018

The HAC program uses a two-year performance period, for the NHSN measures of CLABSI and CAUTI. CMS proposes to wait until FY 2018 to apply the broader versions of the CLABSI and CAUTI measures to this program, which is the first year CMS could feasibly incorporate the rebased measures into the HAC program. The FAH agrees that it would be inappropriate to mix data from 2014, when under the IQR program these measures were reported only for intensive care units (ICUs), with data from 2015, which is the first year during which hospitals must also report infections in locations beyond the ICU. Therefore, delaying the implementation of the newly rebased and expanded measures is appropriate. However, using the rebased and expanded measures in FY 2018 means the HAC program would implement these measures a full year earlier than they would be utilized in the HVBP program. The FAH believes there is value in implementing the rebased CLABSI and CAUTI measures in FY 2019 for both HAC and HVBP.

The FAH also agrees it will be beneficial for the CDC to update the standard population data used to calculate predicted infections for all the NHSN measures to consistently reference 2015.

IV. G. 8. Proposed Extraordinary Circumstances Exception

The FAH supports the proposed extraordinary circumstances exception policy for the HAC Reduction Program. By building on the exceptions process already in place for the quality reporting and value-based purchasing programs, the proposal would allow CMS to provide relief to a hospital if its ability to collect or report accurate quality measure data has been negatively affected as a direct result of experiencing a significant disaster or other extraordinary disaster or circumstance. As noted with respect to the readmission program, CMS should consider expanding the exceptions to include situations in which reporting may be possible, but the impact of the natural disaster or other circumstance on the community is such that performance on the measures may be affected.

Simplified Cost Allocation

IV.H. Proposed Elimination of the Simplified Cost Allocation Methodology for Hospitals

In the NPRM, CMS proposes to eliminate simplified cost allocation methods for hospitals because (1) “Based on FY 2013 data, only 9 of 1,269 CAHs and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology [83 Fed. Reg. at 24,514],” (2) “advances in technology have reduced the cost of recordkeeping, which has allowed hospitals to maintain accurate statistical data and afforded them the flexibility to change to a more precise allocation methodology [id.]” and, (3) the failure to use dollar value as the allocation basis for CT and MRI are distorting cost to charge ratios for those new cost centers. Our members believe that each of these reasons to eliminate the simplified allocation method is inaccurate and does not support the proposed change.
First, CMS has apparently misunderstood its own hospital cost reporting forms in concluding that only 9 CAHs and 23 hospitals currently use the simplified cost allocation method. While it is true that when a hospital first elects this method of cost allocation it must check a “yes” to the question “Was there a change to the simplified cost allocation method?” on Worksheet S-2 (see CMS Pub. 15-02 § 3604, line 45.03), thereafter it is committed under CMS rules to use the simplified method for at least three years. Id. at §3617. But once a hospital makes the election “yes” on question 149 to Worksheet S-2, Part-I, it need not be checked “yes” again. So if in reviewing the FY 2013 cost reports CMS was simply counting the number of “yes” boxes checked to ascertain the total number of hospitals that have elected the simplified method, it could not and did not arrive at a correct count of the number of hospitals using the simplified allocation method. Instead, we verified that for all 2012 through 2014 cost reports in HCRIS, hospitals checked yes 26, 21, and 6 times respectively and that once a hospital answered “yes” it was not repeated in a subsequent year.

To ascertain the number of hospitals that have elected and currently are on the simplified allocation method, filed cost reports would need to be reviewed to determine which hospitals are using the statistics for certain cost centers that are only approved for the simplified allocation method. We accomplished that by reviewing from HCRIS the same 2013 cost reports that CMS reviewed for its conclusions, to determine the number of hospitals that reported a square footage statistic for both the building and major movable equipment cost centers. Square footage would not be used for the major movable equipment cost center absent use of the simplified cost allocation method (unless it was historically used by the hospital before dollar value became the normal approved statistical basis for allocation). We checked the square footage statistic for building and major movable equipment to ensure square footage was used as the allocation basis for both. This would be highly indicative of the use of the simplified method for a large portion of the hospitals with such a match. Using 2013 cost report data, 1977 hospitals match those characteristics. We are thus comfortable with indicating that the elimination of the simplified allocation method would affect a broad swath of hospitals, a significant portion of more than half of the 3212 hospitals that reported statistics for building or major moveable equipment with cost reports in HCRIS for 2013, and far more than the 23 CMS assumed would be subject to this change. So if CMS mandates “dollar value” as the allocation statistic for the major moveable equipment cost center, 1977 hospitals will need to make such a change, not 23.

Second, the elimination of the simplified cost allocation option would create significant and unnecessary administrative burdens on hospitals with little to no impact on hospital reimbursement. CMS specifically recognized the cost savings to hospitals associated with the simplified allocation method when it stated: “This methodology reduces the number of statistical bases a provider maintains. It may result in reducing Medicare reimbursement. A comparison is recommended if the possible lost reimbursement is surpassed by the reduced costs of maintaining voluminous statistics.” CMS Pub 15-2 §3617. This support to allow for simplified allocation methods occurred at a time when the Medicare cost report had a far larger impact on the reimbursement of costs than it does currently. It is troubling that CMS would attempt to impose a more detailed and onerous cost reporting system on providers now, given how

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15 One hospital system that is an FAH member operates 23 hospitals and all 23 use the simplified method to allocate costs. Thus, we have no doubt that CMS’s view of the magnitude of the impact of its proposed change is grossly understated.
little of a provider's actual costs are reimbursed by Medicare through cost report statistics. It is even more difficult to believe that OMB under the Paperwork Reduction Act would approve the requirement to maintain additional and new data under the circumstances based on an unsupported assertion by CMS that maintaining such information is now easy for providers. We outline some of those administrative burdens by applicable cost center below:

**Cost Center:** Movable Equipment  
**Simplified Statistic:** Square Footage  
**Default Statistic:** Dollar Value

Hospitals maintain fixed asset ledgers to track assets owned and to identify the associated depreciation expense. The ledger is a “living document” in that assets are acquired and disposed of throughout the fiscal year. However, at the end of each fiscal year, the ledger represents only those assets owned at that point in time. So, the depreciation expense for the “dollar value” of assets that were owned and depreciated earlier in the year and disposed of prior to the fiscal year end will not be on the ledger. Additionally, a separate Asset Disposal Ledger is usually maintained by hospitals. If hospitals are required to use “Dollar Value,” this change requires an additional reconciliation of ledgers at year end for cost reporting purposes only to ensure that the “Dollar Value” statistic appropriately allocates movable equipment depreciation expense that was recorded during the entire fiscal year. Additionally, Movable Equipment depreciation expense may not be recorded on the hospital’s general ledger in each department where the asset is used but rather in one overall hospital Movable Equipment depreciation expense general ledger account. This situation creates an additional administrative burden for hospital personnel who would then have to attempt to allocate the depreciation expense by department for Medicare cost report purposes only. “Square Footage” is a necessary statistic already maintained by the hospital, it serves multiple purposes because it is used for several cost centers instead of just one and CMS has already concluded that it provides a reasonable and appropriate alternative to using “Dollar Value.”

**Cost Center:** Housekeeping, Social Services, Medical Records and Nursing Administration  
**Simplified Statistic:** Square Footage, Patient Days, Gross Patient Revenue and Nursing Salaries, respectively  
**Default Statistic:** Time Spent

The maintenance and accumulation of time spent by hospital department or other location is a very manual process requiring that affected personnel maintain a daily log of each location and activity throughout the work day. While hospitals may accumulate hours for the noted departments throughout the year in some type of log, this log is typically a manual hard copy document that requires significant administrative burden to be aggregated into a working document to use for Medicare cost reporting purposes. These logs also would require considerably more time to audit and verify than the alternative simplified statistic, in much the same way that MACs have to audit physician and resident time studies. Each of the relevant simplified statistics is already maintained by the hospital, and provides a reasonable and appropriate alternative to using “Hours of Service,” which would cause hospitals to maintain the
voluminous and costly statistics that CMS allowed providers to deviate from over almost the last quarter century.

<table>
<thead>
<tr>
<th>Cost Center:</th>
<th>Laundry and Linen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simplified Statistic:</td>
<td>Patient Days</td>
</tr>
<tr>
<td>Default Statistic:</td>
<td>Pounds of Laundry</td>
</tr>
</tbody>
</table>

The maintenance and accumulation of pounds of laundry by hospital department location is a very manual process. While hospitals may accumulate pounds of laundry throughout the year in some type of log, this log is typically a manual hard copy document that requires significant administrative burden to be aggregated into a working document to use for Medicare cost reporting purposes. Additionally, in many cases, pounds of laundry is not accumulated throughout the year and would only be aggregated for the Medicare cost report. “Patient Days” is a statistic already maintained by the hospital and provides a reasonable and appropriate alternative to using “Pounds of Laundry”.

<table>
<thead>
<tr>
<th>Cost Center:</th>
<th>Cafeteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simplified Statistic:</td>
<td>Salaries</td>
</tr>
<tr>
<td>Default Statistic:</td>
<td>Meals Served</td>
</tr>
</tbody>
</table>

The maintenance and accumulation of meals served by hospital department location is often a very manual process. While hospitals may accumulate meals served throughout the year in some type of log, this log is typically a manual hard copy document that must be aggregated into a working document to use for Medicare cost reporting purposes. In many cases, meals served is not accumulated throughout the year and would only be aggregated for the Medicare cost report. “Salaries” is a statistic already maintained by the hospital and provides a reasonable and appropriate alternative to using “Meals Served”.

<table>
<thead>
<tr>
<th>Cost Center:</th>
<th>Dietary</th>
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</thead>
<tbody>
<tr>
<td>Simplified Statistic:</td>
<td>Patient Days</td>
</tr>
<tr>
<td>Default Statistic:</td>
<td>Meals Served</td>
</tr>
</tbody>
</table>

The maintenance and accumulation of meals served by hospital department location is often a very manual process. While hospitals may accumulate meals served throughout the year in some type of log, this log is typically a manual hard copy document that requires significant administrative burden to be aggregated into a working document to use for Medicare cost reporting purposes. In many cases, meals served is not accumulated throughout the year and would only be aggregated for the Medicare cost report. “Patient Days” is a statistic already maintained by the hospital and provides a reasonable and appropriate alternative to using “Meals Served.”

Finally, CMS asserts in the NPRM that hospitals’ failure to use “dollar value” as the allocation statistic for the CT and MRI cost centers that it mandated in 2011 be added to the cost report has resulted in inaccurate cost to charge ratios for those cost centers. This assertion seems a bit misplaced for two reasons. **First, if only 23 hospitals are using the simplified method to report CT and MRI costs, the cost to charge ratios for these cost centers across the industry should have been little affected by the use of square footage as the allocation**
**statistic rather than dollar value.** But we know from the analysis of 2013 HCRIS data above that a far larger number of hospitals are using the simplified method and square footage as the statistic for those cost centers. Second, a review of the 2013 HCRIS cost reports indicates that only 1721 hospitals have even established a cost center for CT after the CMS mandate for 2011. **We would encourage CMS to focus on compliance with its desire for hospitals to establish those cost centers, and then require the MACs to audit the statistics currently being used to assure they are accurately reported, before it concludes that the problem with these cost to charge ratios is occurring because dollar value as a statistic is not being used.** Additionally, while CMS may believe that using a dollar value statistic is easy with the use of modern technology, the actual experience in the industry, as identified above in our comment regarding the use of dollar value for major moveable equipment, is the opposite.

CMS needs to be clear about its concerns that necessitated this proposal so that alternatives meaningfully designed to address those concerns can be identified. If CMS is proposing to eliminate the simplified allocation method because it is concerned with the underlying data it uses to weight imaging related services in related MS-DRGs, there are better alternatives than disrupting the cost reporting practices of a very large number of hospitals that do not use “dollar value” or cannot accurately now report “dollar value” as the statistical allocation basis for those cost centers. **With a significant portion of the hospitals apparently using dollar value to allocate major movable equipment, CMS could use that data as a reasonable proxy to estimate what the impact would be if all hospitals used dollar value. If such an estimate results in a material difference, CMS could then adjust all of the relative MS-DRG and APC weights to reflect the estimated change in the cost allocation.** Adjusting the cost weights using the available data has obvious advantages in that it corrects the apparent problem immediately, rather than waiting for cost reports to be submitted using the revised allocation methodology, and then audit to ensure the accuracy of the new methodology for almost half of Medicare hospital providers. Also, it preserves the simplified cost allocation methodology that CMS recognized as acceptable and efficient.

For all of the above reasons, we request that CMS withdraw its proposal to eliminate the simplified cost allocation method.

**IV. K. Short Inpatient Hospital Stays**

**Two-Midnight Policy**

In FY 2014, CMS finalized its “two-midnight” policy, which generally considers hospital admissions spanning two midnights as qualifying for IPPS payment. Conversely, the two-midnight policy presumes that hospital stays that occur for less than two-midnights are outpatient cases, unless special circumstances are present. The industry, including the FAH, have expressed concerns about this policy, including how the policy does not seem to align with the traditional Medicare view that patients spending one night in a hospital constitute inpatients.

The Proposed Rule does not propose any changes to the two-midnight policy. Instead, noting ongoing concerns of stakeholders related to the two-midnight rule, the Proposed Rule indicates that hospitals should look to the upcoming proposed rule for the Medicare hospital
outpatient prospective payment system (“OPPS”) for additional discussion. We look forward to reviewing the OPPS rule for this purpose. We are hopeful that the upcoming OPPS discussion on the two-midnight policy will reinstitute greater weight to a physician’s clinical judgment in determining hospital patient status issues and recognize the clinical legitimacy of one-day hospital stays.

**Enforcement Delay**

In light of concerns with the two-midnight policy, CMS implemented an enforcement delay on Recovery Audit Contractors (“RACs”) performing post-payment audits on patient status cases, which Congress extended through September 30, 2015. During this period, Medicare contractors could perform “probe and educate” audits to help hospitals better understand the practical effects of the two-midnight policy. Given that CMS has deferred discussion of any changes to the two-midnight policy to the OPPS rule, we believe the current enforcement delay should be extended until changes are finalized to the policy.

If CMS makes changes to the policy in the CY 2016 OPPS rule, it is unclear whether they would be finalized effective January 1, 2016 or on some other date. Given our members’ prior experience on the two-midnight policy, a transition period should be afforded providers before any new policy is enforced to provide for necessary education and training. So, in this scenario, we urge CMS to extend the current enforcement delay at least through June 30, 2016 or six months from the date of the effective date, if the effective date is other than January 1, 2016.

**Reform for the RAC Program**

The concerns with the two-midnight policy also highlight the need to reform the recovery audit program. We appreciate the incremental reforms that CMS announced in December 2014, although we note that they have not been able to take hold yet due the ongoing litigation involving the next round of RAC contracts. While the FAH appreciates the reforms CMS has announced, we believe the following additional reforms are also important to improve upon a system that unfairly burdens providers and has resulted in a significant backlog of administrative appeals.

- **The scope of RAC reviews should exclude any medical necessity matter involving physician judgment.**

  Medical necessity determinations, including patient status designations, are complex clinical decisions that require physician judgment based upon the facts and circumstances present at the time the decision is made. In particular, patient status determinations are subjective by nature and are made by physicians (not hospitals) with the best interest of patients in mind. However, these decisions are subject to intense scrutiny by RACs, which are financially incentivized to reach the conclusion that the inpatient admission was not justified, often multiple years after the date of service.

  These divergent interests interrupt Medicare payments to hospitals for medically necessary services and create a massive burden on both hospital operations and HHS’ claims
appeals process due to appealed RAC denials, which are frequently overturned. The most direct way to address the problems plaguing HHS and hospitals is to exclude reviews of medical necessity (particularly patient status determinations) from the RAC’s scope of work. It is RAC activity, not hospital behavior that has created the problem we all now face. A similar concern applies to medical necessity reviews conducted by Medicare Administrative Contractors (“MACs”).

- CMS should resolve the conflicting standards addressing patient status determinations in the manual provisions by creating one reasonable, balanced standard.

Due to conflicting manual provisions, there is a lack of clarity regarding the appropriate review standard for Medicare contractors to use when reviewing patient status determinations. We strongly urge CMS to remove the overly stringent standard in the Program Integrity Manual, which is routinely used by RACs. (See §6.5.2(A).) Instead, the appropriate standard should focus on a physician’s clinical judgment based on the facts and circumstances present at the time the physician makes the patient status determination. Additionally, we urge CMS to codify in regulation its prior preamble statement that “. . . the decision to admit should be based on and evaluated in respect to the information available to the admitting practitioner at the time of the admission.” (See 78 Fed. Reg. at 50,952.)

- Additional documentation requests (“ADRs”) should be limited to those where the likely appeals can be resolved by ALJs within 90 days of receipt.

The volume of ADR requests hospitals receive is very significant and has created undue burden for hospitals and the Medicare appeals system. The payment model incentivizes RACs to look at as many claims as possible. The scope of RAC reviews should reach a wide cross section of hospitals, but subject each hospital only to a reasonable number of case reviews that the appeals system can handle within its statutorily-mandated timelines. Additionally, the RAC workload per facility should be proportional to the facility’s overall caseload. We are concerned that the breadth of RAC reviews often is significantly disproportionate to the size of the facility. We believe this recommendation also should be considered for all Medicare contractors.

- Payments to hospitals should not be recouped until after a final resolution of an ALJ appeal confirming an overpayment.

Hospitals view the first two levels of the Medicare claims appeals process as largely meaningless to receiving a fair and impartial review of the merits of their Part A claim. Based upon Office of Medicare Hearings and Appeals’ (“OMHA”) data, the overturn rate for Part A denials at these levels is very low (when removing missing documentation cases). In contrast, the overturn rate at the ALJ level has been high, which confirms the perspective that ALJs provide the first level of real oversight and objectivity to scrutinizing RAC denials.

Currently, alleged overpayments are recouped from hospitals after the second level (i.e., the QIC level) of appeal is completed. Given the substantial time between determinations issued
at the QIC and ALJ levels, as well as the significant overturn rate by ALJs, Medicare contractors should not be permitted to recoup payments from hospitals until after a RAC denial is upheld by an ALJ. Similarly, RACs should not be paid until a final ALJ determination is made upholding their denial.

- **RAC medical necessity denials should be reviewed and approved by a physician on staff at a RAC before being issued to a provider.**

  Our members’ experience is that during ALJ appeals, physician experts employed by RACs often will direct that certain challenged cases be conceded due to lack of support for the RAC denial. Clearly, this action shows that the denials should not have been made in the first place, and demonstrates that RAC physicians must be included in the oversight process at the RAC review’s initial stage. We believe this should be the case for medical necessity reviews conducted by all Medicare contractors. For patient status determinations, it seems especially crucial that a physician’s clinical judgment on whether to admit a patient should be reviewed by a RAC physician before a denial is finalized.

- **CMS should implement an exception to the timely filing requirement which permits hospitals to opt for a Part B payment remedy when faced with a post-payment redetermination which occurs beyond one year from the date of the original claim.**

  We remain concerned about CMS’ decision to strictly apply the timely filing limits in cases where post-payment audits and redeterminations occur after one year from the date of the original claim. In this framework, when RACs review claims that are already outside the timely filing limits, hospitals’ only practical option is to appeal a post-payment denial and seek to have it overturned. We urge CMS to promulgate an exception to the timely filing rules that provides the option for hospitals to rebill the services as Part B outpatient claims when faced with a post-payment review denial. The timeline for exercising this option could be limited, and the post-payment denial date should be the triggering event.

- **CMS should limit the RAC look-back period to original claims filing dates within the prior Medicare fiscal year.**

  The scope and size of RAC reviews is the greatest factor causing the increasing volume of claims appeals by hospitals. Limiting the look-back period will help curtail the volume of reviews and related appeals and reduce the burden on the system as a whole. We agree with CMS’s decision to limit the look-back period for patient status cases to six months, and believe the one year timeframe should apply for all other cases.

- **CMS should enforce the RAC deadlines to issue claims decisions and prohibit RACs from making denials when deadlines are not met.**

  There needs to be dual accountability within the RAC review system. If a hospital does not meet its deadline to respond to an ADR request, then the RAC uses that as a basis to deny the
claim. However, RACs also miss their deadline for issuing decisions, without any repercussions. If RACs miss their deadlines, they should be prohibited from issuing payment denials.

- **RACs should be subject to a financial penalty when their post-payment denials are overturned on appeal at a significant rate.**

  In our members’ experience, RAC denials are overturned often by ALJs, reflecting a pattern of inappropriate denials that should not have been made in the first place and which cost hospitals time, money and resources to challenge and reverse. As a quality control measure, CMS should subject RACs that have significant overturn rates to a financial penalty, and the penalty should extend beyond just recouping their contingency funds for the overturned claims. CMS should establish a threshold of a 10 percent overturn rate to trigger a penalty, and there are various ways that a penalty could be assessed (e.g., based on the total contingency payments for a time period associated with an offending overturn rate.) We welcome the opportunity to collaborate further with CMS on this recommendation.

- **CMS should seek regular stakeholder input with regard to RAC activities.**

  CMS should foster greater transparency and dialogue on RAC matters with the hospital community. Particular steps that can be taken are establishing a designated CMS ombudsman/advocate for hospital concerns on RAC matters; facilitating regular meetings between hospitals RACs, and CMS; more robust reporting on RAC denials, appeals and overturn rates; and, convening a technical expert panel that oversees and advises on the criteria that are used for patient status reviews (until such time as CMS implements a new policy eliminating such reviews).

**Physician Orders**

The FAH requests that CMS revisit and restate when a hospital must have a completed (i.e., a signed or authenticated) physician order for an inpatient admission. Since last year’s CY 2015 OPPS final rule, hospitals have faced uncertainty with regard to the timing requirement for signed hospital inpatient orders.

We urge CMS to resolve this uncertainty and reestablish its long standing policy that inpatient hospital orders must be completed before a hospital can bill for inpatient services, and that such orders need not be complete by the date of patient discharge. We believe this approach best serves patients and reduces the administrative burden on hospitals to obtain physician signatures during what are often very short time periods.

CMS’s regulatory actions appear to have created this uncertainty. When the two-midnight rule was adopted in the FY 2014 IPPS rule, CMS created a new regulation to define an inpatient admission, 42 C.F.R. § 412.3. That regulation contained a subsection (c) that provided: “[t]he physician order also constitutes a required component of physician certification of the medical necessity of inpatient hospital services under subpart B of Part 424 of this Chapter.” The regulatory cross reference is to 42 C.F.R. § 424.13, which at the time required the certification be completed for all inpatient stays before discharge. As a result, a new regulatory
link was created that required completion of the inpatient physician order by discharge, because it was a necessary component of the physician certification.

However, as part of the CY 2015 OPPS final rule, CMS eliminated the physician certification requirement for the majority of inpatient stays, those under 20 days. (See 79 Fed. Reg. 66,770, 66,999 (Nov. 14, 2014).) To effectuate this change, CMS deleted subsection (c) from section 412.3. Thus, the regulatory linkage that required the completion of the physician admission order (signature or authentication) at the same time as certification also was eliminated. Thus, the regulatory text clearly no longer requires a completed admission order by discharge.

Notwithstanding the regulatory change, the 2015 OPPS final rule’s preamble contains a response to public comment that has created uncertainty in CMS’s policy. In its response, CMS states: “[o]ur proposed policy change regarding the physician certification requirements does not change unrelated requirements implemented in the FY 2014 IPPS/LTCH PPS final rule such as the requirements related to the 2-midnight policy. It also does not alter or remove any requirements for hospitals regarding admission orders.” (Id. at 66,999.)

The concern with this statement is that, in fact, CMS did change the regulatory requirement that provided the basis for a policy change that for the first time required that physician admission orders be signed by discharge. It appears the only reason offered in support of maintaining that timing deadline is the following: “[w]e believe that, in most cases, matters relating to the determination of patient status should be resolved before discharge, due to the consequences that flow from such a determination. For example, whether services are billed under Medicare Part A or Part B can have a significant impact on a beneficiary's financial liability.” (Id.)

The FAH understands the premise behind CMS’s response. However, the reality may be quite different: if hospitals cannot get the inpatient admission order authenticated by discharge, the patient will automatically be transitioned to outpatient coverage despite the fact that an inpatient admission order is present in the record and the patient was formally registered as an inpatient of the hospital. In these situations, patients will face Part B deductibles and copays and will not qualify for post-hospitalization skilled nursing services regardless of whether the services otherwise qualified for inpatient coverage. Therefore, the lack of a signature should not be the deciding factor in determining whether a patient’s stay will be billed as an outpatient or an inpatient, especially given the related impact on patients.

On balance, we are concerned the policy espoused in CMS’s response leads to form over substance outcomes which harm patients, and create significant administrative burdens for hospitals to overcome in today’s health care delivery environment. Coupling the policy concerns with the current lack of regulatory basis, we urge CMS to rescind the preamble response that creates the confusion and clarify this policy as requested.
Payment for Observation Services

One concern that has been highlighted by the two-midnight policy is the inadequate payment amount for outpatient observation services. When a patient presents to an emergency room, it is not always clear what the clinical diagnosis should be, yet quality medical care requires that physicians evaluate and monitor the patient to determine whether additional services are necessary. With the Medicare population, these patients often have co-morbidities that complicate that patient evaluation.

There is no denying that both hospital and physician resources are used during this period, yet if the patient does not qualify for inpatient status the hospital receives an inadequate payment (i.e., $1,234.70) for up to 48 hours of care, which is far less than the cost of delivering that patient’s care. Confounding this inequity is the fact that physicians will receive full payment under the Medicare fee schedule for all professional services they render during that time period.

The FAH stands ready to work with CMS to develop a more equitable payment for observation services that reflects the reality of hospital resources utilized during clinically challenging encounters. The difference between an OPPS observation payment and an otherwise applicable medical MS-DRG is very significant, while the hospital resources expended are exactly the same. CMS should address this Medicare payment inequity.

Two-Midnight Policy Payment Reduction

The FAH opposes the standardized amounts proposed for FY 2016 because they continue to include the 0.2% reduction in the IPPS rates that CMS imposed to maintain budget neutrality coincident with implementation of the two-midnight policy. In our comments on the FY 2014 proposed rule when this budget neutrality adjustment was initially proposed, the FAH strongly opposed the reduction, citing both policy and technical concerns. The statutory authority in section 1886(d)(5)(l)(1) of the Social Security Act relied upon by CMS to make the payment adjustment had been used exceedingly sparingly in the past, and there did not appear to be any justification or solid empirical basis for CMS to use it to make a novel, and permanent, budget neutrality adjustment costing hospitals $220 million annually.

CMS stated that the adjustment was based on its estimate using FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net increase of 40,000 inpatient stays. The agency determined that this shift would increase inpatient PPS expenditures by approximately $220 million; and finalized a reduction in the standardized amount, the hospital-specific rates, and the Puerto Rico-Specific standardized amount by 0.2 percent.

CMS did not, however, make any details of its analysis available to the public to support its claim, and thus provided no means for the FAH to comment adequately on the validity of the basis for the proposed adjustments. We noted that projections of the likely impact developed by several of our member hospitals showed that combined Medicare inpatient and outpatient
hospital payments would decrease, not increase, due to the two-midnight policy. During the comment period, the FAH and other hospital stakeholders sought more information from CMS to better understand the methodology and data used to reach this ultimate conclusion, but these efforts did not result in sufficient new information to better evaluate the proposals. Despite hospitals’ concerns and the fact that CMS had not provided sufficient information for the public to review and comment on its methodology and calculations in comparison to our member hospitals’ projections, CMS finalized the 0.2% offset.

In the proposed rule for FY 2015, CMS failed to mention either the 0.2 percent reduction or provide any supporting data that it had relied upon to support the reduction. The FAH submitted a comment in response to the FY 2015 proposed rule, in which it pointed out that CMS had again failed to provide data or other support for implementation of the reduction. The FAH again urged CMS to withdraw the reduction at least until the time it could provide support for the payment reduction that should have been made available in the prior year. In FY 2015 rulemaking, CMS maintained the 0.2% offset without discussion and again without identifying the data, methodology and assumptions upon which CMS had relied to make the adjustment. In the final rule for FY 2014, we had learned that the 0.2% reduction was premised almost entirely on a review of surgical cases, which represented only one-third of total cases, yet the result of that review, the 0.2% reduction, was still applied to the universe of all claims, both medical and surgical. We were disappointed that CMS had not provided data in the FY 2015 proposed rule, as we had expected, based on actual experience under the two-midnight policy to support its position to continue the reduction.

In this proposed rule for FY 2016, CMS again proposes the application of a negative 0.2 percent adjustment to account for the implementation of the two-midnight policy. 80 Fed. Reg. at 24,523 col.3. CMS does not provide any discussion of the two-midnight policy itself or the associated 0.2 percent payment reduction in the FY 2016 proposed rule, and instead states that it expects to include a further discussion of “the broader set of issues related to short inpatient hospital stays, long outpatient stays with observation services, and the related -0.2 percent IPPS payment adjustment in the CY 2016 hospital outpatient prospective payment system proposed rule that will be published this summer.” Id. Thus, CMS has again failed to provide data or other support for continued implementation of such a reduction.

The FAH and others in the hospital community collaborated to model the impact of the two midnight policy. Although we are unable to comment directly on the accuracy of OACT’s estimates due to CMS’s decision not to make any of the data, methods and assumptions about OACT’s calculations available to the public, our analyses clearly demonstrate that, in its first full year of implementation, the two-midnight Policy did not result in a net increase in inpatient stays, as OACT projected. A comparison of FY 2014 and FY 2013 shows a decrease, not an increase, in the number of inpatient cases (see Table 1 below). Specifically, total inpatient discharges declined by four percent and total inpatient discharges of less than two-midnights declined by eleven percent.
Table 1: Percent Change in Inpatient Discharges, FY 2013 to FY 2014

<table>
<thead>
<tr>
<th>Type of Case</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>% Change</th>
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<tbody>
<tr>
<td>Less than 2 midnights</td>
<td>1,179,469</td>
<td>1,053,668</td>
<td>-11%</td>
</tr>
<tr>
<td>At least 2 midnights</td>
<td>8,361,749</td>
<td>8,103,355</td>
<td>-3%</td>
</tr>
<tr>
<td>All cases</td>
<td>9,541,218</td>
<td>9,157,023</td>
<td>-4%</td>
</tr>
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</table>


Our examination of this issue takes into account the fact that the trend line for inpatient admissions was declining prior to implementation of the two-midnight policy. The analysis examined case counts for stays that were less than two midnights and those that were for two or more midnights from FY 2009 through FY 2013, using final rule MedPAR data sets for each year. We determined compound annual growth rates for each of the following time periods:

1. FY 2009-2013;
2. FY 2009-2011 (the time period used by OACT in the FY 2014 final rule); and
3. FY 2011-2013 (a more recent time period for comparison purposes).

Next, we used these growth rates to project a baseline level of inpatient discharges for FY 2014 without the two-midnight policy, and compared these to the actual inpatient discharges for FY 2014, the initial year under the policy. We believe that these differences in discharges approximate the effect of the two-midnight policy. For each of the three scenarios, the comparison suggests that OACT’s estimate that the two-midnight policy would cause a net increase of 40,000 inpatient discharges is wrong and not supported by actual experience. In fact, as shown in Table 2 below, using the longer term FY 2009-2013 growth rate, the two-midnight policy appears to have caused a net decrease of almost 200,000 inpatient encounters.

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16 CAGRs were calculated using the final rule FY 2009 - 2013 MedPAR data since these are complete data. However, since we only have access to the proposed rule FY 2014 MedPAR data at this time, we applied the CAGRs to the FY 2013 proposed rule MedPAR data to maintain consistency between the FY 2013 and 2014 comparison data sets.
Table 2: Inpatient Discharges by Length of Stay and Difference between Actual and Expected Cases Using 2009-2013 Compound Annual Growth Rate

<table>
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<tbody>
<tr>
<td>Less than 2 midnights</td>
<td>1,179,469</td>
<td>1,053,668</td>
<td>-4.2%</td>
<td>1,130,279</td>
<td>-76,611</td>
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<tr>
<td>At least 2 midnights</td>
<td>8,361,749</td>
<td>8,103,355</td>
<td>-1.7%</td>
<td>8,222,870</td>
<td>-119,515</td>
</tr>
<tr>
<td>All Cases</td>
<td>9,541,218</td>
<td>9,157,023</td>
<td>-2.0%</td>
<td>9,353,149</td>
<td>-196,126</td>
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</table>


Although there are many factors that influence the number of inpatient admissions in a given year, these data clearly refute OACT’s projection that inpatient admissions would increase by 40,000 in the FY 2014 rulemaking. Furthermore, this study is consistent with what appears to be OACT’s current assumptions in the table at 80 Fed. Reg at 24,485, and addressed in our uncompensated care DSH comments at page 27, that discharges decreased more than the prior year projections for FY 2014, causing the “Discharge” and “Other” components of the Factor 1 uncompensated care DSH calculation to be dropped from .9855 to .9595, and from 1.0355 to .9993 between the FY 2015 Final Rule and the Proposed Rule.

CMS cannot have it both ways, penalizing hospitals with a decrease in uncompensated care DSH payments because of, according to OACT decreasing total and IPPS hospital discharges and penalizing hospitals for supposed “increasing discharges” in this calculation to reduce the market basket increase. The FAH strongly urges CMS to restore the 0.2 percent reduction for FY16 and compensate hospitals for the FY 2014 and FY 2015 payments lost to the 0.2 percent reductions in those years, which should never have been applied.

Finally, CMS’s decision to address the short inpatient hospital stays and the negative 0.2 percent payment reduction in the CY 2016 hospital outpatient prospective payment system ("OPPS") proposed rule seems to us inappropriate, but it could mislead hospitals on the timing of any appeal of the payment reduction. CMS is required to discuss changes in rates and policies related to the IPPS for a given fiscal year in the proposed IPPS rule for that fiscal year. The summary of the proposed FY 2016 IPPS rule states that CMS is “proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from… continuing experience with
these systems for FY 2016.” 80 Fed. Reg. at 24324. Thus, because the proposed negative 0.2
percent payment reduction related to the two-midnight policy affects IPPS payments, the
reduction must be discussed in the context of this IPPS proposed rule.

CMS cannot simply propose the reduction in the IPPS proposed rule and opt to discuss it
as part of an entirely separate rulemaking document. Doing so would deny stakeholders of a
meaningful opportunity to comment on the reduction at an appropriate time. In fact, CMS’s
statement in the FY 2016 proposed rule that it will address the payment reduction in the FY
2016 OPPS rule may lead stakeholders to believe that they should provide their commentary on
the negative 0.2 percent reduction for FY 2016 in response to CMS’s forthcoming discussion in
the CY 2016 hospital OPPS proposed rule. This would not only be improper, for the reasons
described above, but it is unlikely to have a near-term effect. The IPPS and OPPS payment rates
are finalized on separate timelines. If stakeholders were to comment on the negative 0.2%
reduction to IPPS payments in response to a discussion in the proposed OPPS rule, to be
published in the summer, CMS will likely already be in the process of (or have already finalized)
the IPPS rates, which suggests that those comments will have no relevancy to FY 2016. It also
creates a question if providers wish to challenge the reduction as to whether their time limit to
file such appeals should run from the IPPS Final Rule for FY2016, or from the OPPS Final Rule
where apparently issues related to the reduction will be addressed. CMS should address issues
germane to IPPS rates in the IPPS rulemaking process.

Long-Term Care Hospital PPS

VII.B.3.b. Proposed MS-LTC-DRGs for LTCH Discharges With a Principal Diagnosis of
Psychiatric or Rehabilitation

One of the requirements for an LTCH stay to qualify for payment at the LTCH PPS
standard Federal payment rate under section 1886(m)(6)(A)(ii)(II) of the Social Security Act, as
amended by the PSRA, is that the discharge does not have a psychiatric or rehabilitation
principal diagnosis. CMS is proposing to identify cases with a principal psychiatric or
rehabilitation diagnosis using specific MS-LTC-DRGs and has asked for comments on the
specific MS-LTC-DRGs identified.

The FAH supports CMS in this approach and agrees with the MS-LTC DRGS identified.
These seem to be correctly mapped from the ICD-9 MS-LTC-DRGs.

VII.B.3.d. Determining Whether the LTCH Stay Was Immediately Preceded By a
Discharge From a Subsection (d) Hospital

Both the ICU and ventilator criterion require that for LTCH payment at the PPS standard
Federal payment rate, the LTCH admission must be immediately preceded by a discharge from a
subsection (d) hospital. CMS is proposing that the phrase “immediately preceded” by a
discharge from a subsection (d) hospital means a Medicare patient is discharged from the
subsection (d) hospital immediately prior to the patient’s admission to an LTCH. CMS is also
proposing that the subsection (d) hospital where the patient received inpatient care immediately
prior to the LTCH admission must submit a claim that uses Patient Discharge Status Code 63
(which signifies a patient was discharged or transferred to an LTCH) or Patient Discharge Status Code 91 (which signifies a patient was discharged/transferred to a Medicare-certified LTCH with a planned acute care hospital inpatient readmission). As proposed, if a subsection (d) hospital reports a Patient Discharge Status Code other than 63 or 91, the stay at the subsection (d) hospital would not meet the “immediately preceded” requirement for exclusion from the site neutral payment rate.

The FAH disagrees with this approach and does not believe it is supported by the governing statutory framework. The FAH believes that whether an LTCH stay is “immediately preceded by” a qualifying subsection (d) hospital stay must be determined based on information obtained from claims submitted by the LTCH (except when specifically stated in the statute, including, for example, for revenue codes 020X and 021X for ICU days at a subsection (d) hospital), and not by claim information submitted by other providers. The statute clearly states that an LTCH discharge qualifies for the ICU criterion if the LTCH stay was either (1) immediately preceded by a discharge from a subsection (d) hospital that included at least 3 days in an ICU, as determined by revenue center codes 020x or 021x; or (2) immediately preceded by a discharge from a subsection (d) hospital and the LTCH discharge is assigned to a MS-LTC-DRG for ventilator services of at least 96 hours. The statute does not say that the subsection (d) hospital must submit a claim that uses Patient Discharge Status Code 63 or 91 to qualify for the ICU criterion or the ventilator criterion, nor does it permit CMS to exclude otherwise appropriate and statutorily approved subsection (d) discharges based on the patient discharge status code identified on the claims submitted by the subsection (d) hospital.

The FAH notes that whether and to what extent a discharging subsection (d) hospital reports patient discharge status code 63 or 91 on its claim should not in and of itself serve to disqualify an otherwise appropriate LTCH admission under the ICU or ventilator criterion. It is unreasonable for CMS to hold LTCHs financially accountable and detrimentally impacted by coding practices of providers who treat patients before they are admitted to LTCHs when LTCHs have no ability to control how a prior provider codes a claim or discharge and when data shows the multiple, competing coding challenges experienced by many hospitals.

As the LTCH industry has documented in its comments, Patient Discharge Status Code 63 or 91 are not reliable indicators of whether a patient was discharged from a subsection (d) hospital to a LTCH. This may be due, at least in part, to conflicting and confusing guidance from CMS regarding whether Patient Discharge Status Code 63 should be used for discharges from subsection (d) hospitals to LTCHs. If the agency’s own guidance confuses the Patient Discharge Status Codes for STCH discharges to LTCHs, it is not reasonable for CMS to tie an LTCH’s eligibility for proper payment at the LTCH PPS standard Federal payment rate to whether the STCH that discharged the patient has used a particular patient discharge status code.

The FAH believes CMS should abandon its proposal to require Patient Discharge Status Code 63 or 91 on subsection (d) hospital claims as a pre-requisite to LTCHs being paid at the full LTCH PPS standard Federal payment rate for discharges that otherwise qualify for the ICU or ventilator criterion. Instead, CMS should pay LTCH claims based on LTCH claim data only. The accuracy and propriety of payment to LTCHs should not be dictated by the manner in which another provider completes its claims before the patient is admitted to the LTCH.
If CMS determines it is necessary, it could modify the Medicare claim form used by LTCHs to include fields that allow the LTCH to identify whether the patient qualifies for LTCH PPS standard Federal payment rate payment under either the ICU or ventilator criterion or alternatively, whether the patient should be paid at the site neutral rate.

### VII.B.3.e. Proposed Implementation of the ICU Criterion

Under the new site neutral payment system, an LTCH can qualify to be paid under the LTCH PPS standard Federal payment rate if it has an LTCH admission immediately preceded by a discharge from a subsection (d) hospital that included at least 3 days in an intensive care unit ("ICU"), as determined by the Secretary. CMS is proposing that, for a LTCH discharge to meet the ICU criterion, the subsection (d) hospital must report on the Medicare claim for the hospital stay that immediately preceded admission to the LTCH that the patient had at least 3 days in an ICU using revenue center codes 020X or 021X. CMS has further stated that the subsection (d) hospital claim using revenue center codes 020X or 021X must be consistent with the CMS definition of an ICU under § 413.53(d) in order to fulfill the ICU criterion.

The FAH supports CMS’s proposal that a LTCH discharge meets the ICU criterion if the patient had an immediately preceding stay in a subsection (d) hospital that included at least 3 days in an ICU. We also agree that the Social Security Act, as amended by the PSRA, requires CMS to determine ICU days at a subsection (d) hospital using revenue center codes 020X and 021X, and all subcategories of those revenue center codes.

However, the FAH does not believe the statute permits CMS to limit the revenue center code subcategories under the ICU criterion nor does it think CMS should use or modify the ICU definition at § 412.53(d) in the regulations in a way that restricts the patients who would otherwise qualify for the ICU criterion using the statutorily prescribed revenue codes. This would contravene the intent of the statute and the FAH urges CMS not to consider policies along these lines.

### VII.B.3.f. Proposed Implementation of the Ventilator Criterion

Under Section 1886(m)(6)(A)(iv), an LTCH may qualify to be paid under the LTCH PPS standard Federal payment rate if the LTCH admission was immediately preceded by a discharge from a subsection (d) hospital, and the LTCH discharge is assigned to an MS-LTC-DRG based on the beneficiary’s receipt of at least 96 hours of ventilator services. CMS is proposing that a LTCH must report the procedure code on the Medicare claim to indicate that at least 96 hours of ventilator services were provided during the LTCH stay for the discharge to qualify for the ventilator criterion.

The FAH supports this proposal.

### VII.B.4.a. Reconciliation of Site Neutral Payment Rate

CMS is proposing to require reconciliation of LTCH payments at the site neutral payment rate based upon the LTCH’s cost-to-charge ratio (“CCR”) from the relevant cost report and
charge data. This reconciliation would be done at the time the cost report associated with the discharge is settled.

The FAH does not support CMS’s proposal to require reconciliation of LTCH payments made at the site neutral payment rate. There is no precedent in either LTCH PPS or IPPS for reconciliation of all payments after a cost reporting period has ended. If finalized, the CMS proposal would allow Medicare payment contractors to reconcile all LTCH site neutral payments for every LTCH at the conclusion of every cost reporting period. This is overly burdensome and unnecessary, and erodes the stability and predictability of the PPS payment system. Subjecting all payments to such a “true-up” process potentially years after the end of a cost reporting period is contrary to the statutory intent of a prospective payment system and not required by the statutory framework for the new site neutral payment system. As a result, the FAH believes that CMS should not finalize its proposed regulation at 42 C.F.R. § 412.522(c)(4) or otherwise allow reconciliation of site neutral payments to LTCHs.

VII.B.5. Proposed Application of Certain Existing LTCH PPS Payment Adjustments to Payments Made Under the Site Neutral Payment Rate

- The 25 Percent Rule

CMS is proposing to continue to apply the 25-percent patient threshold payment adjustment policies at 42 C.F.R. §§ 412.534 and 412.536 (i.e., the “25% Rule”) to LTCH discharges that qualify for the ICU criterion or the ventilator criterion. In addition, CMS is proposing to apply these 25% Rule payment adjustment policies to LTCH discharges that are site neutral cases under the proposed regulation at 42 C.F.R. § 412.522(c)(2)(iii),(iv). Under the 25% Rule, discharges in excess of the threshold are paid at an “IPPS equivalent” rate, instead of the much higher LTCH PPS rate.

At a minimum, CMS should not apply the 25% Rule to LTCH cases paid at the site neutral rate. The application of the 25% Rule to these cases is duplicative, unnecessary and punitive. By its terms, the 25% Rule adjusts payments for discharges that exceed the threshold amount to an IPPS equivalent amount. We understand the IPPS comparable per diem amount for calculating payments for site neutral discharges will often be lower and never higher than the IPPS equivalent amount paid under the 25% Rule. As a result, LTCH cases paid at the site neutral rate have already been adjusted to an IPPS comparable rate. Further, because the site neutral payment rate will be a fraction of the traditional LTCH PPS standard Federal payment rate, applying the 25% Rule to those cases paid at the site neutral rate will essentially penalize the LTCH twice for the same case. This can only be viewed as punitive. The FAH urges CMS to abandon its proposal to apply the 25% Rule and its associated payment adjustments to cases paid at the new site neutral payment.

More broadly, as CMS completes the phase-in of the new LTCH patient criteria and payment system the FAH believes that the 25% Rule should be retired in its entirety. The new LTCH patient criteria and two-tiered payment system address the same policy concern that the 25% Rule was initially developed to address – patients who may have been treated in the LTCH setting to maximize reimbursement and not because the LTCH was the most appropriate care setting for the patient. Now that LTCHs will only be eligible for payment at the LTCH PPS
standard Federal payment rate for a subset of historic LTCH patients with LTCH approved, very specific conditions, the FAH does not think the 25% Rule is necessary. CMS itself has recognized, in the FY 2013 LTCH proposed rule, that the development of a new LTCH patient classification system could “render the 25 percent payment adjustment threshold policy unnecessary.” 77 Fed. Reg. 27870, 27879 (May 11, 2012). CMS should stand behind this prior pronouncement and retire the 25% Rule as it fully implements the new LTCH site neutral payment methodology and patient classification system.

- **Interruption of Stay Policies**

CMS also is proposing to apply the interrupted stay payment adjustment policies to all LTCH patients, including both those who qualify for the ICU criterion or the ventilator criterion as well as for those treated as site neutral cases. The FAH opposes CMS’s proposal to apply the interruption of stay policies to LTCH site neutral payment rate cases.

LTCH cases paid at the full LTCH PPS standard Federal payment amount are fundamentally different from LTCH cases paid at the new site neutral payment rate. LTCH cases now paid at the site neutral rate will essentially be paid like IPPS hospital discharges.

For LTCH cases paid in this manner, the policy basis for the LTCH interruption of stay payment adjustments simply do not apply. The 3-day or less interruption of stay policy was developed because CMS believed LTCHs were discharging patients during their course of treatment solely to receive tests or procedures from another facility, only to readmit the patient afterward. CMS also believed that these services should have been provided under arrangement by the LTCH. While this policy may have made sense when LTCHs were reimbursed at a rate substantially greater than STCHs, under the new site neutral payment system, site neutral payment cases will be paid an IPPS comparable per diem rate that is capped at the full IPPS DRG payment plus any applicable LTCH HCO outlier. At this reduced payment rate, the FAH does not believe it is appropriate to apply the policy on 3-day or less interrupted stays, where the LTCH must pay the other facility under arrangement for services provided during the interruption of the LTCH stay.

The greater than 3-day interruption of stay policy is also not supported for site neutral cases. When the LTCH stay is close to the IPPS average length of stay of 4.7 days, it is hard to categorize a 9 day stay at an IPPS hospital as an interruption of the LTCH stay. At the site neutral payment rate, the LTCH is essentially being treated for payment purposes as an IPPS hospital. CMS does not have an interrupted stay policy for discharges from one IPPS hospital to another. IPPS hospitals also do not get only a single payment if a patient is discharged, spends up to 27 days in an IRF or up to 45 days in a SNF and is then readmitted to the IPPS hospital. The LTCH interruption of stay policies were designed for LTCH cases that have a length of stay that is greater than 25 days on average—not for site neutral cases that are expected to have an IPPS-type length of stay on average. Accordingly, the FAH does not support CMS applying the LTCH interruption of stay policies to LTCH cases paid at the site neutral rates.

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• Short-Stay Outlier Adjustment

The FAH agrees with CMS that it should not apply the short stay outlier ("SSO") payment adjustment at 42 C.F.R. § 412.529, or any other SSO payment adjustment, to payments for LTCH cases paid at the site neutral rates.

VII.B.6. Proposals Relating to the LTCH Discharge Payment Percentage

The FAH urges CMS to develop a process to notify LTCHs of their discharge payment percentage through regulations and a formal rulemaking process. This issue is too important and the consequences of not meeting the 50 percent threshold are too severe to relegate to subregulatory guidance the process through which CMS will inform LTCHs. It requires the transparency and public input that notice and comment rulemaking would ensure.

For LTCHs that do not maintain a discharge payment percentage of at least 50 percent in a cost reporting period beginning on or after October 1, 2020, CMS should establish a “cure period” similar to the one that is used to confirm compliance with the ALOS requirement. The FAH also suggests that CMS establish a reinstatement process that allows a hospital to regain its LTCH payment classification after demonstrating over a period of time (perhaps the 5 to 6 month period that is used to establish that an LTCH meets the ALOS requirement) to establish that it satisfies the 50 percent discharge payment percentage requirement. The FAH believes CMS should propose regulations to implement this cure period and reinstatement process well in advance of FY 2021 to allow sufficient time for notice, comment and industry dialogue.

VII.B.7.b. High Cost Outlier Fixed Loss Thresholds Target Amounts and Budget Neutrality Adjustment

CMS has made a number of proposals relative to high-cost outlier ("HCO") cases. First, CMS is proposing to establish separate fixed-loss amounts for cases paid at the site neutral payment rate ($24,485, the same as the proposed FY 2016 IPPS fixed-loss amount) and for cases paid the LTCH PPS standard Federal payment rate ($18,768 based only upon cases that meet the new patient criteria). CMS is proposing to establish two separate HCO targets, one for LTCH PPS standard Federal payment rate cases and one for cases paid at the site neutral payment rate. CMS is also proposing to continue to use an 8 percent target for HCO payments for LTCH standard Federal payment rate cases and to use the IPPS HCO payment target of 5.1 for HCO payments for site neutral payment rate cases. Lastly, CMS is proposing to apply a new budget neutrality adjustment ("BNA") factor of .976996 to cases paid at the site neutral rate.

The FAH agrees with CMS’s proposal to revise the LTCH HCO policy to establish a separate HCO outlier pool (target) and fixed-loss threshold for site neutral payment cases and to use a target amount of 8 percent for HCOs paid using the LTCH PPS standard Federal payment rate. We believe CMS should recalculate and reduce the proposed fixed-loss amount for HCO cases paid under the LTCH PPS standard Federal payment rate to incorporate the cases that were improperly excluded from CMS’s calculation, as explained in greater detail in commentary from the comment letter submitted by Kindred Healthcare. The FAH supports CMS’s proposals to
use the FY 2016 IPPS fixed-loss amount of $24,485 for site neutral payment rate cases, and the same 5.1 percent target as the IPPS for HCO payments to these cases, which are paid based largely on the IPPS for short stay acute care hospitals. The FAH does not believe, however, that CMS should automatically use the IPPS fixed-loss amount and target for site neutral HCO cases every year. Instead, the FAH suggests that once data becomes available following the transition to the new two-tiered LTCH payment system, CMS should calculate the fixed-loss amount and target amount for site neutral HCO cases.

The FAH does not believe CMS should apply a budget neutrality factor to LTCH site neutral cases that qualify for HCO payments. CMS has already accounted for estimated outlier payments for site neutral cases when it adjusted the IPPS payment rate for FY 2016. So to apply an additional budget neutrality factor for these LTCH cases, which are paid at an IPPS comparable rate, amounts to an additional unwarranted reduction in payment, and there is otherwise no precedent for such an adjustment to the annual payment rate determination for the LTCH PPS. The FAH does not think that CMS should, under any circumstances, apply a budget neutrality factor to payments for all LTCH PPS cases to adjust for site neutral high-cost outliers.

VII.C.2.g. Steps for Determining the Proposed FY 2016 MS-LTC-DRG Relative Weights

Each year CMS updates and adjusts the MS-LTC-DRG classifications and relative weights.

CMS established the LTCH cases for FY 2016 rate setting by identifying LTCH cases that would have met the new patient criteria and excluding claims from all-inclusive rate LTCHs, claims from demonstration project LTCHs, and certain Medicare advantage claims. The remaining claims data were used to calculate the proposed relative weights for the LTCH PPS standard Federal payment rate payments for FY 2016.

Based on a review performed by Watson Policy Analysis noted in Kindred’s comment letter, the FAH is informed that there were a number of errors in the methodology employed by CMS in calculating the proposed payment weights, which impacted the LTC-DRG weights, geometric mean length of stay, SSO thresholds, and the HCO fixed-loss thresholds. The FAH urges CMS to review its methodology and the findings of Watson Policy Analysis carefully and to ensure that any methodological errors are corrected when calculating the final weights.

In order to determine the proposed transitional blended payment for site neutral payment rate cases grouped to one of the psychiatric or rehabilitation MS-LTC-DRGs in FY 2016, CMS must assign a relative weight to each of these MS-LTC-DRGs. CMS is proposing to use the FY 2015 relative weights for these 15 psychiatric and rehabilitation MS-LTC-DRGs, since there will be no LTCH cases exempt from the site neutral payments to use in calculating a new proposed relative weight for these proposed MS-LTC-DRGs. The proposed FY 2016 MS-LTC-DRG relative weights are listed in Table 11 of the Proposed Rule.

The FAH agrees with this approach. However, Table 11 to the Proposed Rule shows different weights for these 15 MS-LTC-DRGs than the weights listed in the FY 2015 LTCH PPS Final Rule. The FAH recommends that CMS correct Table 11 in the Final Rule so the
psychiatric and rehabilitation MS-LTC-DRG relative weights for FY 2016 match the weights for the same MS-LTC-DRGs from FY 2015.

In addition to addressing these errors in methodology and correcting the weights in Table 11, the FAH believes CMS should establish two sets of MS-LTC-DRG relative weights for FY 2016, one that will apply to an LTCH that is still subject to the existing single-rate LTCH PPS methodology (for cost reporting periods that begin before October 1, 2015) and one that will apply when an LTCH is subject to the new dual-rate payment methodology (for cost reporting periods beginning after October 1, 2015). This is critical because not all LTCHs will be immediately subject to the new two-tiered payment system. To the contrary, an LTCH with a cost reporting period that begins on September 1, 2015 will not be subject to the new dual-rate payment system for 11 months after FY 2016 begins. Because all of these LTCH discharges will be paid at the LTCH PPS standard Federal payment rate, the FAH urges CMS to set payment weights for these discharges using all LTCH claims in the most recent MedPAR file. This is the same approach CMS used for F 2015 LTCH PPS. There should be no difference in the MS-LTC-DRG reweighting methodology for discharges in cost reporting periods beginning before October 1, 2015. As such, the FAH recommends that CMS establish a second set of MS-LTC-DRG relative weights for FY 2016 for discharges in cost reporting periods that are not subject to the two-tiered LTCH payment system.

Hospital Inpatient Quality Reporting Program

VIII. A.3. Removal and Suspension of Measures

a. Criteria for removing measures. The FAH supports the proposed changes to the criteria for retaining and removing measures from the IQR program. We agree that feasibility in implementing measure specifications is an appropriate consideration in removing a measure, and that alignment with other CMS policy goals is an appropriate basis for retaining a measure.

b. Proposed removal of measures. The FAH supports removal of the two previously suspended measures (Pneumococcal Immunization (IMM-1) and Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (SCIP-Inf-4)). AMI-7a Fibrolynic therapy is proposed for removal because it is a rarely reported. Six other chart-abstracted measures pertaining to stroke and venous thromboembolism are proposed for removal because they are topped-out. We encourage CMS to work with The Joint Commission to develop aligned quality measure sets that focus on those areas with the most potential to improve patient care. We note that for six of the measures proposed for removal, only chart-abstracted versions would be removed; electronically specified versions would be retained, which raises serious concerns. The FAH views on mandatory electronic reporting are discussed in section VIII.8 below.

CMS proposes retaining in the IQR program the influenza immunization measure (IMM-2), even though it has been found to be topped out. While the FAH agrees that IMM-2 is a valuable measure, there may be other measures previously removed from the program that arguably meet the proposed new retention criteria regarding alignment with broader policy goals. CMS should be careful to make consistent decisions about when topped out measures are removed and when they are retained.
VIII. A.6. Proposed Refinements of Existing IQR Program Measures

The FAH does not support the proposed expansion of the 30-day measures of readmissions and mortality measures for pneumonia patients. As noted in section IV.E.4 above pertaining to the readmissions reduction program, we believe that changes proposed for these measures are significant and consideration of the measures for use in public reporting should not be made until the measures have been reviewed and endorsed by the NQF and robustly tested for unintended consequences. In addition, the two proposed new pneumonia measures along with all of the currently endorsed readmission measures should be adjusted for socio-demographic factors. Therefore, the FAH strongly encourages CMS to resubmit all of the readmission measures for which it is the measure steward to the NQF for consideration in the NQF trial period assessing stratification and socio-demographic adjustment.

VIII.A.7. Proposed Additional Measures for FY 2018 and Subsequent Years

CMS proposes the addition of eight new measures to the IQR program beginning with the FY 2018 payment determination. None of the measures have been endorsed by the NQF, and for that reason alone the FAH cannot support addition of these measures to the IQR program. In addition, we have specific concerns about several of the measures.

Hospital Survey on Patient Safety Culture is a proposed new structural measure, which would be reported annually by hospitals through the QualityNet website. Hospitals would provide information on whether (and how frequently) a hospital administers a detailed assessment of patient safety culture using a standardized collection protocol and structured instrument; the name of the survey; whether results are reported to a central location; the number of staff who were requested to complete the survey; and response rates.

Historically, the FAH has opposed the addition of structural measures in the IQR program. A check-the-box measure generally does little to provide actionable information for hospitals and improve patient care. However, we agree that developing a culture of safety is critical for overall quality improvement, and patient safety surveys have proven to be a useful tool for hospitals to use in their overall work to improve patient safety. It may be informative to conduct such a survey on a voluntary basis. However, if CMS proceeds with the addition of a patient safety culture survey, at a minimum CMS should specify which tool(s) should be used and should consider adopting this survey measure as a one-time or periodic survey rather than require ongoing annual reporting. The FAH also encourages CMS to find a means of validating responses on all the structural measures, which can be given less attention given the large number of performance measures in the IQR program. Building more information on the questions into web-based reporting tools would be helpful in preventing inaccurate information resulting from a misinterpretation of the question.

Four new measures of Medicare payments per beneficiary are proposed for specific clinical episodes: kidney/urinary tract infection, cellulitis, gastrointestinal hemorrhage, and lumbar spine fusion/refusion. As discussed earlier in section IV.F.4 above regarding the HVBP
program, the FAH has ongoing concerns about this type of episode cost measure because independent hospitals have limited ability to affect Medicare program spending during the defined episode. In addition, the specific proposed conditions are those for which there are no associated measures of patient outcome or other quality of care indicators in the IQR program. A program payment measure without any associated quality metrics does not provide useful information to hospitals, to Medicare beneficiaries or to other patients seeking information on the Hospital Compare website.

While the proposed new measure of Medicare payment per beneficiary associated with an episode-of-care for primary elective total hip arthroplasty and total knee arthroplasty does have related quality measures (THA/TKA readmissions and THA/TKA complications), this measure should not be proposed for the IQR program until it has been endorsed by the NQF. In addition, this considers episodes extending for 90 days after discharge; it is not reasonable to expect that hospitals can influence total Medicare program expenditures for a 90-day long period after a patient is discharged.

The other two proposed measures would assess post-discharge acute care use including not only readmissions, but also emergency department visits and observation days; one measure addresses acute myocardial infarction patients and the other heart failure patients. While we understand there is interest in assessing whether there is a relationship between use of observation days and readmission rates, we oppose adding these measures to the IQR program. The topic of observation days is being handled through other more appropriate regulatory processes and should not be addressed in a quality assessment measure. If CMS decides to proceed with measure development of these topics, prior to proposing these measures for the IQR program, CMS should submit them for NQF review and endorsement, and in doing so, also include appropriate sociodemographic adjustment. As with readmissions, the need for other acute care services after discharge is likely to be greater among beneficiaries who live in communities with more limited availability of services.

VIII.A.8. Proposed Requirements for Hospitals to Report Electronic Clinical Quality Measures (e-CQM) for the FY 2018 Payment Determination and Subsequent Years

Beginning with the FY 2018 payment determination, CMS proposes required reporting of e-CQMs as part of the IQR program, rather than the current voluntary reporting of e-CQMs. Specifically, for 2018 payment, hospitals would be required to select and submit 16 e-CQMs covering three National Quality Strategy domains from the 28 available e-CQMs; data would be reported for calendar quarters Q3 and Q4 of 2016.

The FAH opposes this proposal for mandatory electronic reporting of quality measures because it is premature. While we support efforts to move toward electronic health record (EHR)-based quality reporting in the future, and to align quality reporting under the IQR with the Medicare EHR Incentive Payment program, the infrastructure is not yet in place to require hospitals to report electronic measures beginning in the last half of 2016. The current e-CQMs are not specified consistently across vendors, and the data they generate is not comparable to the chart-abstracted data on the same measures. For example, some e-CQMs have information gaps, such as missing medication dosage. It is our understanding that in
one case an e-CQM is no longer being supported by the measure steward. As such, the results of the e-CQM measures cannot be effectively used for clinical decision making.

Ongoing technical issues have made it difficult for hospitals to voluntarily report e-CQMs and make it impossible to imagine that mandatory reporting could succeed as soon as next year. For example, a recent snapshot of the Office of the National Coordinator’s JIRA Issue Tracking System website identifies 311 unresolved tickets. In responding to queries about the tracking system, ONC staff indicated that while the goal is to resolve each ticket within 2 weeks, many take longer because they require vetting across multiple vendors, or because measure stewards must be involved and are not available. Issues involving re-publication of standards or measures can sometimes take one year or more to resolve. One of our members recently posted a ticket that took more than two weeks to be placed into assignment, let alone resolved. While we support the direction of electronic quality reporting, mandatory reporting is not possible until issues with consistency of measure specifications are resolved and sufficient resources are devoted to addressing technical issues and eliminating delays in responding to technical concerns. CMS is appropriately engaging in pilot studies of e-CQM submission. This approach should be continued as a means of identifying and correcting current problems.

Further, the proposed IQR requirement for mandatory electronic reporting is proposed even though for purposes of demonstrating meaningful use under the EHR Incentive Program, hospitals are encouraged, but not required to report electronically; attestation will also be accepted as a method of demonstrating meaningful use. While we support efforts to align reporting under the two programs, it is inappropriate to use the IQR program to push for electronic reporting of meaningful use measures. These efforts should continue to be developed through the EHR Incentive Program, and should continue on a voluntary basis until there is evidence that electronic reporting of e-CQMs is a feasible, valid and reliable process. Most importantly, acceleration of electronic reporting under the IQR program is unrealistic given the implementation issues discussed above.

Lack of data validation for e-CQMs is another issue. As part of its efforts to build a platform for electronic data reporting, CMS should also work toward developing a system for validating data submitted electronically. The integrity of the quality reporting and pay-for-performance programs depends on ensuring that data used to calculate hospital performance on measures has been validated. The FAH agrees that data on e-CQMs should not be publicly reported on Hospital Compare until such validation is in place.

The FAH is also concerned that the proposal would undermine the value of Hospital Compare. Of the 28 inpatient e-CQMs, six are required IQR program measures. Under the proposal, when hospitals submit e-CQM data for these six measures, they also would not have to submit chart abstracted data as well. Only when hospitals choose to submit chart abstracted data for one of these measures (presumably because they have met the requirement for 16 e-CQMs using other measures) would those data be reported on Hospital Compare. The proposal would therefore likely result in Hospital Compare data on these measures from very few hospitals, also limiting the data available to calculate national average performance rates, and overall reducing the quality information available to Medicare beneficiaries and others. The FAH supports
continued reporting of all chart-abstracted IQR program measures, even when parallel e-CQMs are being reported.

If CMS intends that e-CQMs are to replace chart abstracted measures, it is important that the e-CQMs are reviewed and endorsed by the NQF before they are adopted for the IQR program. While we recognize that the currently available e-CQMs are those that were adopted for the EHR Incentive Program, the FAH believes that NQF endorsement should be a fundamental requirement of IQR program measures, and there should be no exception. For the future, CMS should work toward NQF endorsement of e-CQMs, which may help in clarifying gaps and inconsistencies in measure specifications.

Finally, we note that the discussion in the Proposed Rule focuses on requiring electronically reporting of e-CQMs in the IRQ program, but creates some confusion surrounding whether this requirement may apply to reporting e-CQMs in the EHR Incentive Program. In the recently proposed EHR Incentive Program Stage 3 rule, CMS discusses that it proposes to continue to encourage CQM reporting through electronic submission for Medicare participants in 2017, and to require electronic submission of CQMs where feasible beginning in 2018 for Medicare providers demonstrating meaningful use. While the FAH looks forward to commenting on any such proposals for 2018, we urge CMS to clarify in the final IPPS rule that reporting e-CQMs under the EHR Incentive Program will be subject to a future rulemaking and is not affected by any proposal in the IPPS rule. This will allow stakeholders an adequate opportunity to comment on appropriate standards for such reporting in the EHR Incentive Program.

VIII.A.9. Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements

CMS is interested in receiving public comments on the potential use of core clinical data elements derived from EHRs in future quality measures. In particular, comments are sought with respect to 1) the use of core clinical data elements derived from EHRs in risk adjustment of outcome measures and other types of measures; 2) the collection of additional administrative variables to enable linkage of EHR data on a patient to claims data for an episode of care (e.g., admission and discharge dates, CMS certification number, date of birth); and 3) use of content exchange standards. With respect to the latter, CMS particularly seeks input on a possible requirement that hospitals use QRDA Category 1 as the standard for transmitting clinical data elements to CMS.

The FAH agrees that there could be value in using EHRs to create a core clinical data set, particularly for use in developing more refined risk adjustment for claims-based quality measures. However, given the problems noted above in submitting e-CQMs, at this point effort should be concentrated on getting the basics of EHR-based reporting straight. Until there is a reliable, consistent, validated method of reporting these data, the envisioned type of core clinical data set could not be successfully implemented.

More generally, in considering future measures for the IQR program and alignment of quality reporting across Medicare and Medicaid quality reporting and payment programs, the
FAH encourages CMS to consider the recommendations of the recent Institute of Medicine report *Vital Signs: Core Metrics for Health and Health Care Progress*. Those recommendations support the development of a streamlined set of standardized measures that would align incentives and actions of organizations across the healthcare system to focus on a limited set of measures.

**VIII.A.10. Form, Manner, and Timing of Quality Data Submission**

The success of the IQR program and the pay-for-performance programs that employ IQR measures depends upon systems that support hospitals in the timely and accurate reporting of measure data. To that end, CMS should ensure that the QualityNet website and the CDC NSHN reporting system have resources sufficient to enable hospitals to report the required data in a timely fashion without service interruptions, and ensure that hospitals are able to retrieve and review the information they have submitted.

One example of ongoing difficulties with these systems reported by our members involves the NHSN measure of C. difficile infection. Systems are reporting that they are unable to access complete information on member hospitals from the NHSN system. NHSN has been helpful in identifying the underlying problem and has given it priority status, but it does not expect to have a permanent fix until July 2015. Hospitals use the data submitted and the resultant reports to improve patient care. They depend on the systems to reliably support those efforts.

Along the same lines, hospitals rely on AHRQ software such as WinQI to monitor performance on the claims-based AHRQ PSI-90 composite patient safety measure. AHRQ is indicating that the ICD-10 technical specifications for AHRQ PSI 90 and an ICD-10 compliant version of this software will not be released until the spring of 2016. This means that once ICD-10 reporting begins on October 1, hospitals will be unable to assess performance on this measure for at least six months.

Finally, the FAH continues to be concerned about the inability of the data warehouse to accept patient-level results for the PC-01, HBIPS and OP-Endoscopy measures. Most of our constituent hospitals use vendors to collect these data and if the CMS data warehouse was fully built-out, these vendors could submit the data on behalf of the hospital just like they do for all of the other Core Measures. Currently, a separate manual process is required of the hospitals to enter their aggregate PC-01, HBIPS and OP-Endo results on the QualityNet website, thereby effectively creating more manual effort and an increased likelihood of keystroke errors. The FAH does not support taking steps to incorporate the collection of the eCQMs into the IQR program until this long overdue work is completed on the warehouse.

**VIII.A.11. Validation of IQR Program Data**

CMS proposes to remove the separate immunization validation stratum it instituted to ensure that every hospital selected for validation would be validated on this VBP program measure. Under the proposal, the Influenza Immunization measure would simply be included in the clinical process of care measure validation stratum, and the validation topic area weights would be modified: the healthcare associated infection topic area weight would remain 66.7
percent; the weight for other/clinical process of care measures would increase from 11.1 percent to 33.3 percent.

As noted earlier, it is important that a validation process be developed for electronic clinical quality measures if as CMS proposes these will replace chart-abstracted measures moving forward. Otherwise these data will not be useful for public reporting or for consideration as pay-for-performance measures.

VIII.C. Proposed Changes to the Long-Term Care Hospitals Prospective Payment System (LTCH PPS) for FY 2016

The FAH appreciates that CMS is under considerable time constraints to implement the provisions of the recently enacted Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. As such, CMS proposes a number of updates to the current LTCH Quality Reporting Program (LTCH QRP) to align the current quality reporting program with the intent of the IMPACT Act. The goal of IMPACT is to align incentives and better facilitate patient care across diverse post-acute settings. The FAH also appreciated the opportunity to participate in the series of stakeholder listening sessions CMS held in early 2015 to gather information and perspectives on the implementation of IMPACT.

The FAH encourages CMS to continue the process of gathering information and feedback on various proposals and to engage stakeholders in additional open listening sessions. The FAH believes the model used to design the initial hospital VBP program is a good model for facilitating efficient implementation of IMPACT. The FAH encourages CMS to develop a comprehensive overall plan for implementation across all settings covered by the IMPACT Act and to hold a broad multi-stakeholder listening session where all interested parties could react to the overall plan looking at its effect on all settings at one time.

Given the scope of changes resulting from the IMPACT Act, it is vitally important that CMS clearly communicate as soon as possible its overall vision for implementation across all settings so that all affected providers, as well as beneficiaries and other stakeholders, have a clear picture of what will change and when the changes will be implemented. The overall strategy for identifying cross-cutting measures, as well as specific timelines for data collection and reporting should be provided with as much lead time as possible. Since the post-acute settings affected by IMPACT often use similar but disparate reporting tools and quality measures, the more clearly CMS communicates proposed changes to the current process and results of any internal testing CMS has undertaken, the confusion will be minimized. While it is important for all post-acute providers to have a complete picture of implementation across settings, the implementation timeline will vary by post-acute provider type, and CMS also should develop setting-specific communications to facilitate understanding of the requirements as the timeline requires.

The FAH applauds CMS for bringing to the MAP the initial set of measures it intends to use to implement IMPACT. The FAH strongly recommends that CMS use only NQF-endorsed measures which are specified for the exact venue in which they will be used. In addition, the FAH strongly recommends that CMS use only those measures recommended by the MAP for application to each specific type of post-acute provider affected. When it is not possible to adopt
the exact same measure with identical specifications across all post-acute settings, reasonably similar and proven reliable measures on the same topic that are NQF-endorsed and recommended by the MAP for each setting should be used.

To satisfy the IMPACT Act quality domains, CMS proposes to adopt three current LTCH QRP measures. CMS refers to input from a Technical Expert Panel (TEP) in reviewing the technical specifications and assessing the applicability of the measure as a cross-cutting measures across post-acute settings. The use of a TEP can be helpful in assessing the data elements of measures and the usability of the measures, but the TEP does not substitute for the rigorous multi-stakeholder input of the full NQF endorsement process. It is also important to note that the MAP support for the proposed measures for the LTCH quality reporting was qualified upon NQF endorsement.

- The FAH supports adoption of the measure “Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay)” for this purpose. This measure has been endorsed by the NQF (NQF #0678), and previously recommended for the LTCH QRP by the MAP.

- The measure “Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)” is NQF endorsed for the nursing home setting and is part of the Nursing Home Quality Initiative as well as the LTCH QRP. As we have stated in the past, the FAH believes this measure should be re-specified for and tested in the LTCH setting and then reviewed by the NQF and endorsed specifically for the LTCH setting prior to finalization in the LTCH QRP program. When pursuing NQF endorsement, CMS should consider risk adjusting this measure, as a number of clinical factors can make patients more vulnerable to falls and affect LTCH performance on this measure.

- The measure “Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function” previously was adopted for the LTCH QRP to begin with FY 2018 payment and is currently undergoing NQF review. The FAH believes implementation of this measure should only proceed if NQF endorsement is obtained, and we are concerned in particular that the measure may not demonstrate sufficient inter-rater reliability for use in comparative quality reporting.

The FAH strongly recommends that CMS modify the CARE Data Set to collect the needed measure data. Trained clinicians will be required at admission and discharge to assess and numerically score the level of independence demonstrated by patients on several assessment items such as self-care, mobility, cognition, communication and bladder continence. The LTCH CARE Data Set includes a six-level rating scale. LTCHs will be measured on the proportion of their patients with complete assessment data, and not on the actual changes in functional status scores between admission and discharge. Such a scoring scheme does not address the purpose of the measure. The FAH encourages CMS to rethink this tool and not to finalize it in this rule.

The final report of “The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set” indicates the CARE tool is challenged by poor response rates and that data specifications continue to remain a
problem. In particular, there are indications that facilities did not submit data on certain elements either because they did not apply to their patient population or because the timing of the data submission does not fit the timing of how care is delivered to LTCH patients.

The risk adjustment of functional improvement also could be very challenging because key elements were missing data at rates from 27 to 35 percent. Capturing cognitive status via observational assessment within two days of admission is also questionable. The results of Pilot 1 and Pilot 2 show variability in results. Clinicians familiar with the patient need to be making the assessments on the cognitive items. The TEP raised these concerns, but no adjustments were made in the assessment timetable to improve the validity of the collected data.

Finally, the FAH recommends that the proposed functional status measure, NQF 2631, be limited to patients that qualify under the ICU criterion or the ventilator criterion for the LTCH PPS standard federal payment rate. We agree with CMS that these patient have complex medical care needs for an extended period of time. Because of this, LTCH patients often have limitations in functioning because of the nature of their conditions, as well as deconditioning due to extended bed-rest and treatment requirements. The previously adopted 30-day all-cause unplanned readmissions measure has now been endorsed by the NQF (NQF #2512). However, it still does not include socio-demographic risk adjustment.

Therefore, we encourage CMS to risk adjust this measure, and all readmission measures, to take sociodemographic factors into account. Research, such as the study cited earlier in this letter by Jeph Herrin of Yale University and others, has shown that community factors outside the control of the hospital significantly affect the likelihood of a readmission. The FAH also encourages CMS to submit a sociodemographic risk adjusted and stratified measure to the NQF trial period process for review.

In addition, the chart at the bottom of Page 24599 of the proposed rule indicates the measure will become effective for payment year 2017 when the text on that same page indicates it will be effective for FY 2018 payment determinations. CMS needs to clarify the discrepancy in implementation timing for this measure.

Public reporting of some LTCH QRP measures is proposed to begin in the fall of 2016 for four measures: CLABSI, CAUTI, pressure ulcers and all-cause readmissions. The FAH supports public reporting of the CLABSI, CAUTI and pressure ulcer measures, all of which are NQF endorsed. However, we again note that public understanding of hospital performance on the unplanned readmissions measure would be greatly enhanced if CMS pursues modifications to the risk adjustment of the readmission measure to appropriately reflect hospital-level variation resulting from sociodemographic factors.

The FAH supports the CMS proposed changes to the data submission timeframes for LTCH QRP measures. Under the proposal, LTCHs will be required to submit data 4.5 months (approximately 135 days) after the end of a calendar year quarter rather than the current 45 day submission period. The proposal would become effective fourth quarter of CY 2015 to meet reporting requirements for FY 2017 LTCH QRP and would continue for FY 2018 and beyond. The FAH agrees that this proposal would align data submission and correction deadlines with other quality reporting programs and facilitate public reporting.
Public reporting of LTCH QRP data is proposed to begin in the fall of 2016 and LTCHs would be given a 30-day period to preview their data. The FAH supports the development of a reporting and preview process. However, the FAH strongly encourages CMS also to permit LTCHs to submit data corrections during the preview period. The CMS proposal as presented does not include an opportunity to submit corrections to the data. Rather, CMS states that its proposal to extend the data submission period for LTCH data will give LTCHs sufficient opportunity to review and submit corrections to their data.

The large majority of the other quality reporting programs administered by CMS permit providers to submit data corrections in conjunction with the data preview period. The process of collecting and reporting quality measures is time and resource intensive. By combining the data submission and data review/correction periods, CMS reduced the allotted time that LTCHs have to collect and submit their data. Therefore, the FAH strongly encourages CMS to permit LTCHs to submit data corrections during the data preview period.

Public reporting for LTCHs is proposed to be included on Hospital Compare. While there is logic to having all hospital reporting on one public reporting site, the FAH believes it will be difficult to distinguish LTCH hospital quality measures and results from those of short-stay acute care hospitals. The data sets are distinct and the FAH is concerned that a single site would be confusing to those using Hospital Compare. Consequently, the FAH recommends CMS develop a separate, distinct LTCH quality reporting display with robust descriptions of the type of patient and severity of the illness encountered in an LTCH.

Outlier Payments

Addendum II.A.4.g. Proposed Outlier Payments

For FY 2016, CMS has proposed a case be eligible for high cost outlier payments when the cost of the case exceeds the sum of the of the prospective payment rate for the diagnosis related group (“DRG”), any indirect medical education (“IME”) and disproportionate share hospital (“DSH”) and Uncompensated Care payments, any add-on payments for new technology and $24,485. The present threshold, which has been in effect since October 1, 2014, is $24,626. This represents a nominal change year over year. CMS indicates that it has used the same methodology to calculate the fixed loss threshold as it has in the prior two years. Just as with last year’s rule-making we are concerned with the lack of transparency associated with the agency’s assessment of the charge inflation component of the fixed loss threshold calculation as we explain below. We expect that this threshold will decrease by the final rule based on updated information, particularly updated cost to charge ratios (“CCRs”). Since 2009, every final outlier threshold has been lower than its related proposed threshold, and on average the reduction between the proposed and final threshold has exceeded five percent. We address in more detail our concerns below.

The thresholds for FYs 2015 and 2016, final and proposed, represent an approximate twelve-percent increase over the outlier threshold CMS used for FY 2014, without any explanation by CMS that could be justified by data it made available to commenters to explain why the threshold would need to increase by such a large amount between FY 2014 and the last two periods, to approximate the 5.1% target for outlier payments as a portion of
total DRG payments. We are particularly concerned about the magnitude of the increase given that for FY 2014, when the threshold was set at $21,748, Watson Policy Analysis (“WPA”), see the attached report Summary of Research Modeling FY 2016 Proposed Inpatient Prospective Payment System Outlier Payments (Attachment) at pp. 4-5, indicates that outlier payments as a proportion of DRG payments will be about 5.26%, only nominally above the target percentage. Given there is no reliable information for how well the FY 2015 outlier threshold causes such payments to meet the 5.1% target, \(^{18}\) it seems to us speculative at best that such increases in the threshold are warranted.

A. CMS’s Charge Inflation Calculation Lacks Transparency and Prevents Adequate Notice and Comment.

The only justification that CMS offered for the increase in the FY 2015 threshold was that it had measured significant charge inflation between FY 2013 charges and the period covered by the final rule. See 79 Fed. Reg. at 28321-23. CMS used a two-year charge inflation factor of 11.5% for that rule. For FY 2016, CMS proposes to use a lower two-year charge inflation factor of 9.8%. Yet the slight $141 reduction in the threshold from the final FY 2015 threshold to the proposed FY 2016 threshold does not coincide with the much more significant decrease in anticipated charge inflation. We hope and expect that once CCRs are updated from data used for the Final Rule that this disparity will be rectified.

Telling for the FAH and problematic for purposes of our comments last year, we noted that for purposes of measuring charge inflation CMS used first quarter FY 2015 (fourth quarter calendar year 2014) claims data that has not been released to the public. Because CMS would not make this data available to us or to our consultant, we had no way to test CMS’s measure of charge inflation and had to accept that measure for purposes of modeling the threshold and preparing that comment. CMS acknowledges it withheld last year’s charge inflation data in this proposed rule, 80 Fed Reg. at 24,632 col.3, and in response provides a new table with quarterly total charges and claims data for the eight quarters used in this proposed rule. Unfortunately that data is only provided in totals and the source of the data is not identified so it cannot be tested for accuracy or reliability.

Our consultant WPA reviewed charge and claims data for the first seven quarters contained in the new table from CMS and attempted to match it to available MedPAR data.\(^{19}\) WPA is unable to match the figures in that table from publicly available data sources and CMS has not otherwise made the underlying data available, or any guidance that describes whether and how it edited such data to arrive at the total of quarterly charges and charges per case it used to measure charge inflation. Consequently, the table provided in the proposed rule is not useful in assessing the accuracy of the charge inflation figure that CMS uses in the proposed rule to calculate the outlier threshold. In the absence of such data and how it was edited by CMS to arrive at the totals used in its charge inflation calculation, CMS has violated a principal tenet of the APA by not providing adequate notice to allow for meaningful comment.

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\(^{18}\) Indeed to the extent there is any information about how well the FY 2015 threshold met its 5.1% payment target, that information indicates the threshold, as we commented for the FY 2015 rulemaking, was set to high. CMS indicates in this proposed rule that it estimates outlier payments for FY 2015 will approximate 4.88% of MS-DRG payments. 80 Fed. Reg. at 24,634 col.3.

\(^{19}\) The last quarter of charges and claims totals from CMS is not yet covered in MedPAR.
B. Calculation Of Actual Outlier Payment Percentages Based On Actual Historical Payment Data

The FAH believes it is absolutely critical to the process for setting the outlier threshold that CMS accurately calculate prior year actual payment comparisons to the 5.1% target. It is impossible for CMS to appropriately modify its methodology to achieve an accurate result if it is not aware of, or misinformed about, the magnitude of inaccuracies resulting from prior year methodology. For example, in the proposed rule for FY 2014, CMS indicated that using partial year data for FY 2013 CMS estimated that outlier payments would equal about 5.17% of MS-DRG payments. Yet in the FY 2015 rule-making CMS indicated that for FY 2013 CMS it will have paid outliers at 4.81% of MS-DRG payments. Thus, CMS’s early estimate for FY 2013 was too high, as has often been the case. Similarly, in this year’s proposed rule, 80 Fed. Reg. at 24,634 col.2 CMS states:

In the FY 2015 IPPS/LTCH PPS final rule correction notice (79 FR 59681), we stated that, based on available data, we estimated that actual FY 2014 outlier payments would be approximately 5.68 percent of actual total MS–DRG payments. This estimate was computed based on simulations using the FY 2013 MedPAR file (discharge data for FY 2013 claims). That is, the estimate of actual outlier payments did not reflect actual FY 2014 claims, but instead reflected the application of FY 2014 payment rates and policies to available FY 2013 claims.

Our current estimate, using available FY 2014 claims data, is that actual outlier payments for FY 2014 were approximately 5.34 percent of actual total MS–DRG payments.

We are concerned that CMS thought it was over shooting its target amount for FY 2014 by .58% and this motivated CMS to dramatically increase the threshold for FY 2015, only to learn this year that its estimate was grossly overstated. WPA’s use of even more current data indicates that even the amount indicated in the proposed rule for FY 2014 is overstated. See WPA Report at Analysis 3, pp. 4-5. It critical that CMS not allow the use of incomplete data from prior years to color its calculation of current period thresholds.

C. Using Most Recent Data To Calculate The Threshold

We also note that with each rulemaking, the final outlier threshold established by CMS is always significantly lower that the threshold set forth in the proposed rule. While the FAH can only speculate as to why this consistently occurs, the FAH believes the decline is most likely due to the use of updated CCRs or other data in calculating the final threshold. This again emphasizes that CMS must use the most recent data available when it calculates the outlier threshold. Table A below expresses that trend graphically.
Table A

<table>
<thead>
<tr>
<th>FY</th>
<th>Final</th>
<th>Proposed</th>
<th>Variance</th>
<th>% Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>$20,045</td>
<td>$21,025</td>
<td>$(980)</td>
<td>-4.66%</td>
</tr>
<tr>
<td>2010</td>
<td>$23,140</td>
<td>$24,240</td>
<td>$(1,100)</td>
<td>-4.54%</td>
</tr>
<tr>
<td>2011</td>
<td>$23,075</td>
<td>$24,165</td>
<td>$(1,090)</td>
<td>-4.51%</td>
</tr>
<tr>
<td>2012</td>
<td>$22,385</td>
<td>$23,375</td>
<td>$(990)</td>
<td>-4.24%</td>
</tr>
<tr>
<td>2013</td>
<td>$21,821</td>
<td>$23,630</td>
<td>$(1,809)</td>
<td>-7.66%</td>
</tr>
<tr>
<td>2014</td>
<td>$21,748</td>
<td>$24,140</td>
<td>$(2,392)</td>
<td>-9.90%</td>
</tr>
<tr>
<td>2015</td>
<td>$24,626</td>
<td>$25,799</td>
<td>$(1,173)</td>
<td>-4.76%</td>
</tr>
</tbody>
</table>

With regard to the current rule-making we note for example that CMS has used data from the December 2014 PSF file, but that at the time the proposed rule was issued, the March 2014 PSF file was available. We had WPA attempt to replicate CMS’s methodology in setting the threshold using the same data CMS indicates it used for the proposed threshold. Correcting for the revised transfer weights, WPA was able to replicate the threshold within $126, accepting CMS’s charge inflation factor as accurate only because it could not replicate that factor due to a lack of supporting information for CMS’s calculation. Thus, we have high confidence that WPA understands CMS’s methodology and has accurately modeled that methodology such that inputting more current data will yield a threshold that will be more likely to meet the target percentage of 5.1%.

D. Accounting For Outlier Reconciliation

The FAH has repeatedly requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold. In the Proposed Rule, 80 Fed. Reg at 24,633, col. 2, CMS addresses its decision not to consider the impact of outlier reconciliation in its determination of the outlier threshold as follows:

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2014 outlier payments, we are not proposing to make any adjustments for the possibility that hospitals’ CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier final rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year.

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20 CMS issued a corrected proposed outlier threshold of $26,337 on the 6/11/12 in 77 Fed. Reg. at 34,328, but references the noted lower figure in the FY 2013 final rule as its corrected proposed outlier threshold in the FY 2013 Final Rule, 77 Fed. Reg. at 53,696.
The FAH has concerns regarding CMS’s decision not to consider outlier reconciliation in developing the outlier threshold and its failure to provide any objective data concerning the number of hospitals that have been subjected to reconciliation and the amounts recovered during this process. We are certainly aware that in February 2003, the Secretary signed an emergency interim final regulation that would have corrected the outlier threshold to account for reconciliation, but that the rule was not issued because of objections from the Office of Management and Budget. If it was possible to correct the outlier threshold at the time reconciliation was first being proposed, it is difficult to understand why, with ten years of reconciliation experience that cannot be accomplished. We are particularly concerned with CMS’s failure to consider adjusting for reconciliation this year given CMS’s projected charge inflation factor of 9.8% over two years, which if costs were held constant would suggest that a significant number of hospitals could be subject to reconciliation. We developed the following Table from HCRIS.

### Table B
**Historical Outlier Reconciliation Payments Using the 1996 HCRIS File**

<table>
<thead>
<tr>
<th>Federal Fiscal Year (FY)</th>
<th>Total Number of Cost Reports</th>
<th>Outlier Reconciliation Payments ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>4,044</td>
<td>(351,892)</td>
</tr>
<tr>
<td>2004</td>
<td>3,877</td>
<td>(19,082,757)</td>
</tr>
<tr>
<td>2005</td>
<td>3,651</td>
<td>(5,358,217)</td>
</tr>
<tr>
<td>2006</td>
<td>3,517</td>
<td>(61,204,479)</td>
</tr>
<tr>
<td>2007</td>
<td>3,524</td>
<td>(11,403,869)</td>
</tr>
<tr>
<td>2008</td>
<td>3,489</td>
<td>(6,967,494)</td>
</tr>
<tr>
<td>2009</td>
<td>3,471</td>
<td>(5,102,232)</td>
</tr>
<tr>
<td>2010</td>
<td>2,248</td>
<td>536,515</td>
</tr>
</tbody>
</table>

One of our consultants also attempted to develop the same information for FYs 2010-13 data using the March 2014 update of the HCRIS file and the CMS 2010 Hospital Complex Cost Report Instruction Manual. Following the instructions on page 176 of the instruction manual an effort was made to extract outlier reconciliation payments. However, none of the cost reports had the payment information populated in these fields. We are puzzled as to why this data is not being captured as instructed. The FAH again requests that CMS disclose in the final IPPS rule and future proposed and final IPPS rule making the amount CMS has recovered through reconciliation by year. Historical information that provides the total amounts recovered by the program through reconciliation each year since the inception of reconciliation would provide a baseline and trend information to assess whether reconciliation is a significant factor to be considered in the development of the outlier threshold. The information will allow the FAH and others to comment specifically on how this provision would impact the threshold. Absent the disclosure of data showing that the recoveries obtained through the reconciliation process are immaterial, the FAH requests that CMS consider these recoveries in its determination of the outlier threshold in the final and future rule making and to be transparent about the amounts involved in that process.
The FAH is not proposing a threshold this year. While we have confidence in the work of WPA, its work is dependent on a large variable in the outlier calculation, charge inflation, that we cannot verify from the limited information that CMS has provided related to the proposed rule. In addition, we recognize that with the release of the MedPAR Final data with additional claims, which will lead to new weights being calculated and with updated cost to charge ratios, it is appropriate to recalculate the Fixed Loss Threshold from the data that will be released with the final rule.

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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,
Summary of research modeling

FY 2016 Proposed Inpatient Prospective Payment System

Outlier Payments

Date: June 2, 2015

Introduction

Watson Policy Analysis (WPA) was asked to analyze issues and replicate outlier payments from the Centers for Medicare & Medicaid Services (CMS) Fiscal Year (FY) 2016 Inpatient Prospective Payment System (IPPS) proposed rule. In short, this outlier policy sets forth a set of rules whereby CMS provides payment to inpatient hospitals for a portion of their high cost inpatient cases once particular thresholds are met. CMS describes its methodology and logic starting on page 24631 of the Federal Register.\(^1\) We attempted to replicate the CMS logic, then compared our results and made a variety of adjustments to assess the impact of using different parameters. This report summarizes our findings.

Summary

A summary of findings is as follows:

- WPA was able to come reasonably close to the CMS calculation of the Fixed Loss Threshold (FLT). WPA estimated actual outlier payments for FY2014 at $24,611 compared to the CMS published $24,485.
- WPA analyzed CMS’ charge inflation calculation and did not identify anything in the calculation based on the data presented. However, there is not clear information or data provided to allow the underlying numbers used in the calculation to be able to be replicated and/or tested for accuracy.
- WPA calculated an actual outlier payment proportion of 5.26% versus the 5.34% reported in the rule for FY 2014. As a part of the rate-setting, the target percentage is intended to be 5.1%, and it may be in some years that the target is exceeded.

Background on outlier payments

In the IPPS program, CMS has established the concept of “outliers” to be high cost cases which are paid an additional amount so that providers’ potential losses are limited. When the estimated costs of a case exceed the payment for the case, plus a threshold, CMS will generally

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\(^1\) "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program" Federal Register Vol. 80, No. 83, Thursday, April 30, 2015
pay 80% of the costs that exceed the payment plus the threshold. CMS pays 90% for discharges assigned to one of the “burn” diagnosis related groups (DRGs).

This threshold is known as the “fixed loss threshold” (FLT) and is set prospectively with each rule based on a target that operating outlier payments will be 5.1% of total operating payments, including outliers. This target is determined by simulations of expected payments.

Background from CMS on outlier payments can be found at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html

Additional detail is provided by CMS each year in the IPPS rule.

**Analysis 1: Replication of the CMS estimated FY 2016 outlier payment from the FY 2016 IPPS proposed rule**

WPA estimated payments, including outlier payments from the FY 2014 Proposed Medicare Provider Analysis and Review (MedPAR) Proposed File, following the methodology set forth in various IPPS rules. In modeling payments, WPA used information from the following data sources:

- MedPAR FY 2014 proposed file: contains inpatient hospital claims from FY 2014 that were used by CMS to model proposed FY 2016 payments,
- Table 5 – Weight file: contains the proposed weights for FY 2016,
- Impact file: contains hospital specific characteristics and payment factors,
- DSH Supplemental File: contains uncompensated care per claim payment amounts for providers,
- The FY2016 Proposed IPPS rule in particular information on cost and charge inflation factors, and
- Inpatient Provider of Services File: contains provider specific information.

In addition, other factors such as charge inflation, CCR adjustment factors, and standardized payment amounts from the proposed rule were used.

Complete payments were calculated including operating, capital, disproportionate share hospital (DSH), indirect medical education (IME), uncompensated care, etc. for each case, following the CMS methodology. The CMS methodology excludes sole community hospitals, hospitals that have become Critical Access Hospitals (CAHs), and Maryland hospitals.

WPA calculated a fixed loss threshold of: $24,611 versus the published number of $24,485, a difference of about 0.515%.

As a part of this replication, there are some methodological notes:

- The originally released impact file did not contain information identifying which providers were subject to payment reductions due to quality measures or meaningful use of electronic health records (EHR). As a work-around, we first modeled it using that information from the Inpatient Provider of Services file. Once CMS added that
information to the impact file, we modeled it using the impact file. The different data sources did not make a material impact on the calculation of the FLT.

- Although the average uncompensated care per claim data is in both the impact file and the DSH supplemental file, the reported values were not always the same between the two files. We used the DSH Supplemental File.

- Although we have been able to replicate the final calculation for the charge inflation factor with the data presented in the rule, it is not possible to replicate the underlying numbers that are presented in the rule. CMS published numbers without releasing the full underlying data that went into those numbers or detail on their methodology (such as what data was included in the numbers, or the data cleaning that may have taken place.) Indeed the first seven quarters of data in the new table do not coincide with the most recent releases to the MedPAR file. The eight quarter of data is not publicly released at all. Therefore, there is the unverifiable assumption that the charge inflation data is correct. In addition, there is no opportunity to comment on the exact details of the methodology used to create those numbers because CMS has not released a description of the exact methodology. In order to replicate and comment on the methodology, sufficient information must be given so that it is possible for others to replicate the logic and get similar results.

Please note that the FLT will adjust with the release of the final rule and associated files.

**Analysis 2: Comparison of Cost-to-Charge ratios from the FY 2016 proposed rule Impact file and the Inpatient Provider Specific File**

As part of the analysis, we compared the CCRs included in the impact file (used in modeling the FLT) with the CCRs from the Provider Specific File (PSF).

Comparing the 3,444 providers listed in the impact file and a simulated December 2014 PSF file, we had a match rate of 89.56% (3,085 providers). When comparing the impact file provider list and the March 2015 PSF, we had a match rate of 61.6%.

For the December 2014 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was -0.02% if all providers were used, and -0.36% if just those providers with differences were used.

For the March 2015 comparison, the average difference in operating CCRs between the impact file and the PSF file (weighted by the number of discharges) was 0.19% if all providers were used and 0.48% if just those providers with differences were used.

The table of matching statistics reported last year in a report from The Moran Company – “Modeling Fiscal Year 2015 Inpatient Prospective Payment System Outlier Payments” dated June 23, 2014 is as follows:

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2 Note: The PSF file for December 2014 was removed before the IPPS rule was released and not downloaded. So as an approximation, we took the March 2015 and restricted it to records in the PSF file prior to 1/1/15, to simulate a December 2014 PSF file.
<table>
<thead>
<tr>
<th>Final Rule for FY</th>
<th>Matching Rate Between Impact file and Most recent PSF CCRs</th>
<th>Average Percent Difference Between the Impact File and Most Recent PSF Operating CCR of the Same Hospital (weighted By Discharges)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010*</td>
<td>93.2%</td>
<td>0.4%</td>
</tr>
<tr>
<td>2011*</td>
<td>96.4%</td>
<td>0.1%</td>
</tr>
<tr>
<td>2012 - Dec 2010 Update</td>
<td>96.9%</td>
<td>0.2%</td>
</tr>
<tr>
<td>2012 - March 2011 Update</td>
<td>65.3%</td>
<td>1.6%</td>
</tr>
<tr>
<td>2013</td>
<td>92.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>2014</td>
<td>97.2%</td>
<td>-0.1%</td>
</tr>
<tr>
<td>2015a - Dec 2013 Update</td>
<td>98.8%</td>
<td>-2.7%</td>
</tr>
<tr>
<td>2015a - March 2014 Update</td>
<td>64.8%</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

a Proposed Rule
b March PSF updates available at the time the FY 2010-2013 Final Rules were issued; December 2012 PSF update for the 2014 Proposed Rule and December 2013 Update for the 2015 Proposed Rule

Note that WPA developed new programs to analyze the data, so there may be differences with the previous analyses by The Moran Company and Vaida Health Consulting. However, the matching percentage calculated by WPA is within a similar matching percentage as that calculated by the Moran Company. In addition, the average difference in operating CCR is much smaller.

**Analysis 3: FY 2014 Outlier payment using FY 2014 MedPAR data**

In order to examine the actual outlier payments, WPA modeled payments and combined outlier payment information to estimate the actual payments. CMS published an estimate that outlier payments were 5.34%. The chart below shows operating payments and the outlier payments that we calculated. The operating payments and the total are based on the modeling simulation. The outlier payment amount is from the reported outlier payments from the MedPAR 2014 Proposed File. In the simulation using the CMS FLT we estimate that outlier payments are 5.27%.
### Analysis 4: Outlier payments from Medicare cost reports, 2015 update

Using the Medicare cost reports (HCRIS) from December 2014 and March 2015, WPA calculated the estimated outlier percentage for FY 2013 and FY 2014. We followed the general logic of previous years.

The table from previous years (from The Moran Company report) is:

<table>
<thead>
<tr>
<th>Federal Fiscal Year</th>
<th>Number of Cost Reports Beginning in FFY</th>
<th>IPPS Payments Net of IME, DSH and Outlier Amounts ($)</th>
<th>Outlier Payments ($)</th>
<th>Outlier Payment Level (%)</th>
<th>Target Outlier Payments (5.1%)</th>
<th>Shortfall in Outlier Payments ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>3,072</td>
<td>79,733,087,154</td>
<td>3,660,488,700</td>
<td>4.39</td>
<td>4,284,918,277</td>
<td>(624,429,577)</td>
</tr>
<tr>
<td>2011</td>
<td>2,973</td>
<td>77,197,362,245</td>
<td>3,707,407,929</td>
<td>4.58</td>
<td>4,148,646,443</td>
<td>(441,238,514)</td>
</tr>
<tr>
<td>2012</td>
<td>2,716</td>
<td>67,461,311,753</td>
<td>3,137,279,264</td>
<td>4.44</td>
<td>3,625,423,498</td>
<td>(488,144,234)</td>
</tr>
<tr>
<td>2013</td>
<td>43</td>
<td>431,689,902</td>
<td>13,367,119</td>
<td>3.00</td>
<td>23,199,352</td>
<td>(9,832,233)</td>
</tr>
<tr>
<td>Total (2009-2013)</td>
<td>8,804</td>
<td>224,823,451,054</td>
<td>10,518,543,012</td>
<td>4.47</td>
<td>12,082,187,570</td>
<td>(1,563,644,558)</td>
</tr>
</tbody>
</table>

Using the HCRIS data from December 2014 and March 2015, WPA calculates the following equivalent factors.³

³ Note: New programs were developed by WPA, so it is possible they are not completely consistent with the previous analyses done by The Moran Company. To help show the distinction, the results are displayed separately here.
Note that these numbers are subject to change as more hospitals submit cost reports and also cost reports are reviewed and revised.

**Analysis 5: Fixed Loss Threshold over time**

From examining the fixed loss threshold in proposed rules and final rules, there is a pattern of the fixed loss threshold declining. The following table shows the fixed loss thresholds for recent years.

<table>
<thead>
<tr>
<th>FY</th>
<th>Final</th>
<th>Proposed</th>
<th>Variance</th>
<th>% of Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>$20,045</td>
<td>$21,025</td>
<td>$ (980)</td>
<td>-4.66%</td>
</tr>
<tr>
<td>2010</td>
<td>$23,140</td>
<td>$24,240</td>
<td>$ (1,100)</td>
<td>-4.54%</td>
</tr>
<tr>
<td>2011</td>
<td>$23,075</td>
<td>$24,165</td>
<td>$ (1,090)</td>
<td>-4.51%</td>
</tr>
<tr>
<td>2012</td>
<td>$22,385</td>
<td>$23,375</td>
<td>$ (990)</td>
<td>-4.24%</td>
</tr>
<tr>
<td>2013</td>
<td>$21,821</td>
<td>$23,630</td>
<td>$ (1,809)</td>
<td>-7.66%</td>
</tr>
<tr>
<td>2014</td>
<td>$21,748</td>
<td>$24,140</td>
<td>$ (2,392)</td>
<td>-9.90%</td>
</tr>
<tr>
<td>2015</td>
<td>$24,626</td>
<td>$25,799</td>
<td>$ (1,173)</td>
<td>-4.55%</td>
</tr>
</tbody>
</table>