September 6, 2016

The Honorable Andy Slavitt
Acting Administrator
Center for Medicare and Medicaid Services
CMS 1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

Acting Administrator Slavitt

On behalf of the Healthcare Billing and Management Association (HBMA) we are pleased to submit these comments on the 2017 Medicare Physician Fee Schedule Proposed Rule.

HBMA

HBMA is a non-profit trade association of companies providing medical billing and related services to physicians, hospitals, non-physicians (ambulance, DME, ASC, IDTF, Rural Health Clinics, FQHCs, etc.) and other health care organizations throughout the United States. For nearly twenty years, HBMA has been the recognized billing industry organization for education, advocacy and cooperation in all matters that affect the processing of provider claim-related data, compliance and management services. It is estimated that our member companies process in excess of 350 million claims annually and serve virtually every clinical specialty, in every setting, in every state.

Our members include companies with over three thousand employees and dozens of branch offices as well as small businesses with solo practices as clients.

For over fifteen years, HBMA has worked closely with CMS and other federal agencies on all matters related to Medicare, including but not limited to, billing rules, payment policy and compliance. We have provided comments, testimony, private and public input related to patient privacy as well as offering a wide array of education materials, conference programs, references, announcements and targeted training for our member companies and their employees and clients.

Our members routinely assist their physician clients with the transition, implementation and compliance with Medicare rules and regulations and strive to be a trusted advisor and reliable source of expertise on the Medicare program's requirements.

It is estimated that as many as a third of all claims submitted on behalf of physicians are submitted by an HBMA member company. Our Association's members are intimately involved in the preparation and submission of Medicare claims to every MAC Contractor, Carrier and

DMERC on behalf of providers in every state and U.S. Territory. We have reviewed the NPRM and prepared comments on some of CMS' proposed rules that specifically affect our members, their provider clients and/or their individual or shared responsibilities.

A. Procedures Subject to the Multiple Procedure Payment Reduction (MPPR)

Since January 1, 2012, the professional component (PC) of advanced imaging services has been subject to a 25 percent reduction known as the Multiple Payment Procedure Reduction (MPPR). The reduction applies when multiple imaging procedures are furnished by the same physician (or physician in the same group practice) to the same patient, in the same session, on the same day. Full payment is made for the PC of the highest priced procedure. Payment for the PC of subsequent services is reduced by 25 percent.

The Consolidated Appropriations Act of 2015 revised the payment reduction from 25 percent to 5 percent, effective January 1, 2017. CMS is proposing to implement these provisions for services furnished on or after January 1, 2017.

HBMA fully supports this policy and is pleased that CMS is moving ahead with the implementation of this provision in accordance with the statutory requirements.

B. Revaluation of 10- and 90- Day Global Surgical Packages

In the CY 2015 PFS final rule CMS finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre and post-operative visits and performance of the surgical procedure. However, the Medicare Access and CHIP Reauthorization Act (MACRA) prohibited the Secretary from implementing the policy established in the CY 2015 PFS final rule.

CMS has developed a process to gather information needed to value surgical services and is proposing a rigorous data collection effort that you believe would provide the data needed to accurately value the 4,200 codes with a 10- or 90-day global period.

CMS is proposing to gather the data needed to determine how to best structure global packages with post-operative care that is typically delivered days, weeks or months after the procedure and whether there are some procedures for which accurate valuation for packaged post-operative care is not possible. Finally, CMS believes the data would provide useful information to assess the resources used in furnishing pre- and post-operative care.

CMS proposes a three-pronged approach to collect timely and accurate data on the frequency of, and inputs involved in furnishing, global services including the procedure and the pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment. The effort would include:

- Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.

- A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
- A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

HBMA agrees that the CMS surgical package concept is problematic for a number of reasons and that this approach has advantages over previous proposals.

We also strongly encourage CMS to consider **specialty specific** statistically valid analysis of current practice. This could easily be accomplished by selecting the most common surgical procedure claims and auditing records for the subsequent 10 or 90 days. We believe this would be the least disruptive and most accurate analysis. We stress current claims as post payment audits that look back in time may not accurately reflect current practice or patient populations.

Finally, CMS has identified several codes that should be used as part of the data collection process:

Inpatient

GXXX1 Inpatient visit, typical, per 10 minutes, included in surgical package.
GXXX2 Inpatient visit, complex, per 10 minutes, included in surgical package.
GXXX3 Inpatient visit, critical illness, per 10 minutes, included in surgical package.
Office or Other

Outpatient

GXXX4 Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package.
GXXX5 Office or other outpatient visit, typical, per 10 minutes, included in surgical package.
GXXX6 Office or other outpatient visit, complex, per 10 minutes, included in surgical package.

Via Phone or Internet

GXXX7 Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package.
GXXX8 Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package.

HBMA believes the proposed HCPCS codes do little to provide the information CMS is seeking. All have specified durations of 10 minutes, which is not a reasonable measure. The actual time may be significantly more or less.

With the exception of GXXX4, an office or outpatient visit by clinical staff that could mirror 99211, there is no relationship between the proposed code descriptions and any E/M level of service.

We believe these proposed codes will lead to even more confusion and widely variable data as physicians attempt to subjectively categorize what the terms; typical, complex and critical mean in terms of post-operative visits.

If CMS elects to pursue this proposal, clearly defined descriptions, consistent with CPT E/M terminology and all levels of E/M service need to be established.

HBMA believes the data collection methodology CMS will rely upon should utilize existing methodology (i.e. claims-based) to the extent possible to avoid putting additional administrative burden on providers.

Furthermore, survey data should be collected in such a way that you can disaggregate the responses by specialty.

C. Appropriate Use Criteria for Advanced Diagnostic Imaging Services Provider-led Entities (PLEs)

Section 218(b) of the Protecting Access to Medicare Act (PAMA) directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services.

HBMA agrees with CMS and the medical community that the purpose of this initiative is to provide meaningful and relevant diagnostic exams with the objective of only performing them when achieving an appropriate level of medical necessity.

However, as we try to codify what was once the individual practitioner's best judgement based on his/her education, training and experience, we run the risk of creating many unintended and illogical consequences that impede the drive for improved quality and cost improvements. More importantly, we are potentially undermining the public's confidence in the clinical decision making skills of the ordering professional and implicitly suggesting that a computer program can be substituted for the judgement of a highly educated health professional. Where does it end?

And, from an operational perspective, we are adding rather than reducing administrative complexity, burden and costs to the healthcare system.

The "good news" is that Qualified Clinical Decision Support Mechanisms (CDSMs) are going to replace 3rd party benefit administrators whose decisions seemed –at best – arbitrary. By requiring that QCDSMs are produced by "Provider-led Entities" (PLEs), we dramatically improve the practitioner and patient confidence that the decision making tool is using medical criteria based upon clinical evidence rather than a "business" decision made by company intent on denying coverage, regardless of the clinical consequences.

With that in view, we nonetheless agree and support the use of CMS's approach to utilizing Provider-led Entities (PLEs) to establish and maintain Qualified Clinical Decision Support Mechanisms (CDSMs).

CMS states in the NPRM that it

> *"has received feedback from stakeholders that CDSM should contain a comprehensive collection of AUC, incorporating individual criteria from all specified AUC libraries, while others suggested it is better to start with a CDSM that contains AUC for a few clinical areas."*

CMS also states that

> *"both approaches have merit and the best approach could depend on a particular care setting. CMS believes the program should maintain flexibility, and it envisions a number of AUCs developed by different PLEs."*

HBMA agrees with CMS's vision of maintaining flexibility and multiple AUCs by different PLEs, especially during the early years of implementation of these criteria.

As these processes and policies mature, the HBMA sees value in consolidation of "like PLEs" to promote consistency in application of AUCs across all providers and geographic regions. The degree to which flexibility expands multiple criterion for similar or like procedures, administrative simplification is diminished, audits are made unnecessarily complex and additional and unnecessary time and resources are necessary to maintain continuing compliance.

With regard to the "implementation" of the chosen methodology, we strongly urge CMS to use a stair step or phased approach to developing and implementing a timeline.

More specifically, we recommend the implementation be logical, thoughtful and digestible. This has been one of the major barriers to efficient implementation to many past programmatic changes such as PECOS and ICD-10. In both instances, inadequate planning led to multiple, lengthy delays costing CMS and the provider industry millions of additional dollars.

To achieve this, diagnostic imaging provides a unique opportunity to divide and conquer the implementation in that the specialty is already divided into subspecialties by modality (Computerized Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), etc.)

We believe this represents an opportunity to first implement one modality, trouble shoot and adjust for all the unknown (and unknowable) barriers that will inevitably turn up. The "lessons" learned can be applied to the next modality and so one and so on until all advanced imaging is covered.

For example, the first modality might be CT exams. The initial period of time for the first modality might be six months with a definitive date to proceed with Magnetic Resonance Imaging (MRI) beginning the seventh month, adding NM the 10th month and continuing with the remaining modalities one year from the inception of the implementation of the CT exams.

HBMA members have experienced many similar implementations in our own operations. From our collective experience one of the keys to effective change management is a pragmatic approach to identifying and adopting achievable goals within reasonable timelines and minimizing delays and additional costs. We believe this "stair step" approach would help CMS and the provider community achieve those efficiencies and even provide a framework for future large scale and holistic implementations.

CMS has stated that it seeks input on how appropriateness ratings by CDSMs could be interpreted and recorded for the purposes of this program.

As CMS states in preface to discussing this issue in the proposed regulations

> *"Two key aspects of that discussion remain relevant to the CDSM component of this program. First, AUC, and the CDSMs through which clinicians access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery."*
>
> *"By adhering to common interoperability standards, CDSMs could both ensure integration of patient-specific data from EHRs, and allow clinicians to optimize the time spent using the tool."*

HBMA passionately supports CMS's position that the entire structure and viability of using CDSMs to apply approved Appropriate Use Criteria "requires" adherence to common interoperability standards.

The lack of enforcement of existing standards from prior laws and regulations such as the standardized transaction code sets established in the 1996 HIPAA legislation continues to plague the industry (governmental and commercial) with inconsistencies and inefficiencies 20 years post legislation. Because commercial carriers tend to follow CMS standards as they are established, it is imperative that this standardization "precede" implementation of AUC in CDMS to achieve optimal outcome

In regard to the specific question asked reading appropriateness ratings, CMS states:

> "*There are different views about the comprehensiveness of AUC that should be accessible within CDSMs. Some stakeholders believe that the CDSM*

should contain as comprehensive a collection of AUC as possible, incorporating individual criteria from across all specified AUC libraries. The intent would be for ordering professionals to avoid the frustration, experienced and voiced by many clinicians participating in the MID, of spending time navigating the CDSM only to find that no criterion for their patient's specific clinical condition exists.

Other stakeholders believe, based on decades of experience rolling out AUC in the context of robust quality improvement programs that it is best to start with a CDSM that contains AUC for a few clinical areas where impact is large and evidence is strong. This would ensure that quality AUC are developed, and that clinicians and entire care teams could fully understand the AUC they are using, including when they do not apply to a particular patient.

HBMA agrees and supports CMS's recommendation to be flexible in its approach to implementing appropriateness ratings.

While CMS may later determine increased opportunities to streamline or consolidate appropriateness ratings by CDSMs, allow the flexibility to exist at the inception of the process, HBMA believes will increase the success of CMS's implementation.

HBMA supports and appreciates CMS deferring that ordering professionals will not be required to consult qualified CDSMs by January 1, 2017. HBMA also recognizes that CMS may further delay such implementation even beyond the January 1, 2018, date referenced in the proposed rule. The operational and administrative retooling that will have to occur for those performing the advanced imaging service are numerous.

Our colleagues involved directly in performing advanced imaging have suggested that it could take as long as 18 months from the date it is announced for compliance with the AUC/CDS initiative to be fully ready. We have no reason to dispute their conclusions.

With regard to adopting procedures for capturing CDSM derivative information on claims forms, CMS states it believes an AUC consultation must take place for every order for an applicable imaging service furnished in an applicable setting and under an applicable payment system.

Specifically, CMS seeks comments on the following five (5) considerations and following each are HBMA's comments:

1. Specific operational considerations it should take into account

   Each of the following criterion has a substantial body of knowledge and workflow associated with the topic.
   For purposes of responding to this rule and recognizing the depth and breadth of the discussion items, **HBMA would welcome the opportunity to interact with CMS on the operational issues you have identified.** Without knowing the answer to the

questions you have posed, it would be almost impossible to provide meaningful comments speculating on the possible outcomes.

Once CMS has made some decision on the direction it intends to take, **we STRONGLY encourage CMS to convene a stakeholders group to work through the myriad operational and administrative issues associated with the new policy.**

2. Information on barriers to implementation along the timeline that allows ordering and furnishing professionals to be prepared to consult AUC and report consultation information on the claims.

    a. **All of the items listed in number one (1) previously represent multiple subsets of barriers in both substance and timelines.**

3. Whether separate rulemaking outside the payment rule cycle is preferred.

    a. **HBMA believes that separate rulemaking outside of the annual Physician Fee Schedule rule timetable would be welcome for any instances in which adjudication and payment of the claim are not dependent on the documentation of that information (i.e. – data gathering and aggregation for quality improvement, etc.)**

    b. To the extent that approval of a claim is interdependent or otherwise impacted by rulemaking, HBMA believes it would be advantageous to keep such rules fully integrated with the physician fee schedule rulemaking process.

4. Whether information should be collected using HCPCS level II G Codes or HCPCS modifiers.

    a. **HBMA recommends that "only the minimum necessary information" required to approve a claim be a definitive part of the claim form.**

        i. There are many other elements of the medical care workflow that exist and precursors to a claim being filed.

            1. For example, a patient has a symptom, a physician may see the patient, then an order is requested for another physician to see the patient, then the 2nd physician orders a diagnostic exam with an order. The medical necessity leading to the diagnostic exam may be complex. Adding more and more information to the claim form to "assure" compliance is counterproductive to the mandate of Administrative Simplification.

HBMA strongly recommends CMS press for Administrative Simplification and NOT require more documentation commensurate with service and seek alternative

methods for extracting non-payment based information and using other procedures to confirm compliance of the provider community.

Exceptions of the Consulting and Reporting Requirements

> *"Furthermore, we recognize that most encounters in an emergency department are not for an emergency medical condition as defined in section 1867(e)(1) of the Act.*"

HBMA members represent tens of thousands of emergency and radiology physicians. Because of our intimate familiarity with ER and Imaging billing, we neither understand nor agree with CMS's position.

Under EMTALA, when a patient presents in an emergency department, the law requires that ER staff examine, triage, diagnose stabilize and/or treat that patient. To place a restriction (by absence of this exception) that creates potential time delays for emergency physicians to have to follow time intensive decision making processes while in the midst of the chaos of attending to multiple patients in trauma is a disservice to Medicare patients and the physicians that serve them.

CMS states *"the clinician only needs to determine that the medical condition manifests itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in: placing the health of the individual (or a woman's unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part."*

CMS seems to believe that by mirroring the EMTALA definition of "emergency medical condition" you are not adding to the administrative or clinical burden.

We would disagree with this conclusion.

Although Emergency Departments and Emergency Physicians have well-developed triage system for determining if EMTALA applies, the triaging system will likely err on the side of see and treat rather than discharge.

EMTALA is a treat/release policy, not a payment policy. If CMS wished to adopt a commonly used ER policy as a proxy for appropriate use, then a more relevant proxy would seem to be the "reasonable person" rule applicable to insurance company's covering ER visits.

Under this approach, CMS would exempt from application of AUC any patient for whom the patient had a reasonable belief they were in need of emergency care.

D. Prohibition on Billing Qualified Medicare Beneficiary Individuals for Medicare Cost-Sharing

CMS is using the MPFS to remind providers of the prohibition from collecting Medicare Part A and B deductibles, coinsurance or copayments from beneficiaries enrolled in the Qualified Medicare Beneficiaries (QMB) program.

QMB is a Medicaid program which helps certain low-income individuals with Medicare cost-sharing liability. In 2013, approximately 7 million Medicare beneficiaries were enrolled in the QMB program.

We are not surprised by the findings of the 2015 study cited in the proposed rule. However, we question the value of the report's findings of the need to re-educate providers about proper billing practices for QMB enrollees.

Physicians and hospitals do not want to improperly bill patients. The administrative and operational costs of returning improperly collected money is often more than the additional money collected by the provider. This is certainly true for physicians.

Identifying those patients who are Qualified Medicare Beneficiaries is, we believe, at the heart of the problem. Medicare does little to assist providers in identifying those patients who are dually eligible for both Medicare and Medicaid and thus classified as QMBs. Reminding providers that they are prohibited from collecting Medicare deductibles from QMBs is appropriate but unless CMS improves the ability for providers to identify these patients, the reminders will do little to curb this problem.

For example, the Medicare Explanation of Benefits (EOB) reports the crossover but as this would be reported electronically, software would need to identify when it crossed over a claim to a payer that the software doesn't know exists. To our knowledge, medical billing/practice management software does not do this and this would require a systems change for most software.

If QMB claims are posted manually, staff would need to be trained to recognize that (1) the EOB is identifying a crossover (2) there is no secondary indicated in the patient's account (3) identify that the crossover is Medicaid (4) check Medicaid eligibility to determine that the patient is a QMB and not some other form of Medicaid.

Whether software or manual posting, overhead is significant. Much of this could be eliminated if the *Medicare* card identified the person as a QMB. We recognize that this is difficult in that an individual's Medicaid eligibility status may change monthly.

The problem isn't that providers need "reminding" that they are prohibited from collecting Medicare deductibles from QMBs, it is that they do not know that the patient is a QMB.

As there are only two entities who know the individuals QMB status – Medicare and the patient – CMS should also undertake efforts to notify beneficiaries who are QMBs that they fall into this status and that the patient should notify their providers of their QMB status.

E. Recoupment or Offset of Payments to Providers Sharing the Same Taxpayer Identification Number

Medicare Administrative Contractors (MACs) have the authority to offset or recoup overpayments made to Medicare providers. Furthermore, they have the power to withhold payments from a provider that shares a TIN with a delinquent provider in order to satisfy the debt.

MACs are required to supply a provider with timely notification, in writing, of their intention to fully or partially offset or recoup payment. The notification must include the reasons for the offset or recoupment. However, CMS is proposing that it will not send a written notification to all providers under the TIN that their payments might be affected to satisfy the overpayment another provider under the same TIN.

Currently when a recoupment is with a provider utilizing the electronic remittance advice (HIPAA transaction 835) there is not enough information in the ERA that these can be accounted for in the form of an electronic workflow. In order to remove the administrative burden of a manual intervention, there must be a way within the electronic transaction to identify not only the patient and date of service that the money is being taken from, but also the reason for the recoupment. Claims within the 835 electronic transaction paid under this scenario may be "paid", but the cash is not reflected due to the recoupment and accurate electronic posting of these files often requires manual intervention.

We recommend that CMS establish a technical workgroup that would bring together stakeholder representatives to develop operational policies and changes to facilitate the electronic exchange of this information.

Under section two, "timely manner" should be identified.

Historically, there has not been consistency in the notification of provider and the actual recoupment. By giving a specific, strictly enforced, timeline in which the obligated provider has the opportunity to return the money or contest the recoupment, it would provide a cleaner accounting of refunds to CMS from the obligated provider. This would eliminate the need to recoup the overpayment from any related applicable provider.

HBMA recommends a timeline of 120 days.

As previously noted, both the applicable and the obligated providers must be notified of intended recoupment. From an accounting perspective, physician compensation may or may not be affected due to the recoupment, based upon the physician compensation arrangement. In addition, depending on the type of practice involved, significant recoupments would potentially affect the financial statements. Also, if the number of overpayments were outside of what would be the normal occasional situation, this would be reason that a practice would need to identify

why this is happening. Without notification, this situation might not be identified nor addressed to reduce future occurrences.

The terms "obligated" and "applicable" provider are not common nomenclature in the healthcare industry. In order to assure a clear understanding and to facilitate the tracking system of Medicare overpayments on the corporate level, HBMA recommends CMS use the terms "rendering or billing provider" for the obligated provider and "related entity" for the applicable provider.

Finally, we recommend that CMS change the word "a" to "any" provider of services in the description of applicable provider.

F. Value-Based Payment Modifier and Physician Feedback Program

Under the Value-Based Modifier (VM) program, CMS is required to issue feedback reports to participating providers. The VM is being phased in and does not yet apply to physicians in groups of less than 10 eligible providers or solo physicians. However, effective January 1, 2017, the VM will apply to all providers.

Providers are allowed to request informal reviews of their VM adjustment determinations. The informal reviews could result in improved performance scores for either of the two components of the VM: the quality composite and the cost composites. CMS is proposing to update the informal review process in the MPFS.

Under current policy, if an informal review for the quality composite results in a determination that CMS made an error in its initial calculation, the provider TIN would be upgraded to an "average quality" score. CMS is updating its policy so that if a provider receives an average quality score as a result of an informal review determination due to one of several internal CMS issues described in the MPFS, that they are also not penalized for having a "high cost" determination.

CMS is proposing that if a provider receives an average quality redetermination from an informal review but had originally been given a "high cost" on their cost composite score, that provider would have their cost composite score improved to "average cost."

HBMA encourage CMS to limit the downward performance based payment adjustment for at least two years, as physicians are trying to adapt and understand how measures will be applied under MIPS.

In the NPRM, CMS notes that it was "*unable to determine the accuracy of PQRS data submitted via EHR and QCDR for the CY 2014 performance period, due to data integrity issue*s."

This gives us grave concerns and must be addressed moving forward. This finding also warrants the continuation of claims-based reporting for the foreseeable future.

In the NPRM, CMS reports that after the release of the 2014 Annual QRURs CMS discovered that for the 2016 VM calculations, only claims from January 12 through December 31, 2014, were identified; claims from January 1 through January 11 were incorrectly omitted.

Because this omission accounted for a relatively small percentage of CY 2014 claims CMS concluded that re-running QRURs and recalculating the quality composite was not practical or possible.

This error is not, in our opinion, insignificant. Certainly for the providers whose scores may have been adversely affected by this omission.

This finding was very disconcerting.

The diversity and magnitude of the errors, the potential for it to occur in the future, the timing of when CMS becomes aware of an error, and practical considerations (i.e. potential need to compute a final VM upward payment adjustment factor after the performance period has ended) is very significant.

Identifying an error of this magnitude, two years after it occurs, will create uncertainty for groups and solo practitioners about their final VM payment adjustment making it difficult for them to plan and make forecasts.

Given the history of errors and miscalculation of PQRS and VBM performance – it provides more evidence to justify a postponement of the proposed MIPS Quality Reporting until Q4 of 2017 so CMS has the additional time necessary to develop safeguards that will prevent similar issues in the future.

CMS must devote more time and resources to correcting their data collection and reporting methods to allow greater transparency.

CMS acknowledges that there is high demand for informal reviews. This is not surprising given the lack of transparency in this process. CMS should be aware that providers have a difficult time matching their own performances with those of the QRUR reports.

HBMA recommends that Providers be given at least 120 days from the date of release of their QRUR report to submit their request for an "informal review".

Conclusion

On behalf of the Healthcare Billing and Management Association, we appreciate this opportunity

to comment. Please do not hesitate to contact us if you have any questions or need any additional information or clarification of any of our recommendations.

Sincerely,

Holly Louie, CHBME
President
HBMA