Holland & Knight

MEMORANDUM **July 10, 2015**

Re: CMS Releases CY 2016 Medicare Physician Fee Schedule Proposed Rule

CMS released July 8 the proposed rule for the CY 2016 Medicare physician fee schedule (PFS). The proposed rule will be published in the Federal Register on July 11, 2014. **CMS will accept comments until September 8, 2015.**

The proposed rule sets 2016 Medicare payments rates for physician services, including a modest payment increase as a result of SGR repeal under the Medicare Access and CHIP Reauthorization Act (MACRA).

CMS estimates the impact on total allowed charges to be relatively neutral for most specialties, with a few exceptions: independent laboratories and pathology are expected to see a 9 percent and 8 percent increase, respectively, while radiation oncology, radiation therapy centers and gastroenterology will see a decrease at -3 percent, -9 percent and -5 percent, respectively.

CMS is required to implement the 2014 Protecting Access to Medicare Act (PAMA), which calls for the agency to find 1% worth of cuts in 2016-2018 by identifying misvalued codes. The agency has proposed about 0.25% cuts, but it has made clear that more cuts will come in the final rule to meet that 1% threshold. Affected services will include radiation therapy and GI. The conversion factor for CY 2016 is estimated to be $36.1096.

With the repeal of the Sustainable Growth Rate (SGR) formula in MACRA, CMS is seeking comments on various components that have not been defined, such as types of metrics and benchmarks that will be used in evaluating eligible professional performance.

In the interim, CMS has established criteria for the 2016 performance year for the value-based payment modifier (VBPM), which could result in penalties of 4% in 2018 for high cost/low quality providers. The proposed rule also details criteria for 2016 performance in the Physician Quality Reporting Sytem (PQRS) to avoid a 2% penalty in 2018. Through 2018, providers should expect PQRS and VBPM to proceed at the current pace, with all providers—including non-physicians—subject to VBPM adjustments by 2018.

Other key highlights include:

Improving the Valuation and Coding of the Global Package: In the 2015 MPFS Final Rule, CMS finalized transitioning all 10-day and 90-day global codes to 0-day codes, however, MACRA prohibited CMS from implementing this policy. MACRA requires that instead, CMS develop a process to gather information needed to value surgical services from a representative sample of physicians and data collection should begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery as appropriate. Therefore, CMS is seeking input from stakeholders on the kinds of objective data needed to increase the accuracy of the values for surgical services. CMS is also seeking comments on the potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and post-operative care.

***Physician Quality Reporting System (PQRS*)**: For 2016 PQRS reporting, CMS is not proposing to make any major changes to reporting via claims or registry. Therefore, providers reporting via claims or registry would be required to report 9 measures (including one cross-cutting measure), covering at least 3 National Quality Strategy domains, and report each measure for 50% of their Medicare Part B Fee-for-Service patients seen during the reporting period. Providers reporting via registry could also report 1 measures group on 20 patients (more than 50% of which must be Medicare Part B patients).

Changes to the Physician Value-Based Payment Modifier (VBPM) in CY 2018: The VBPM will expire after 2018 with the implementation of the MIPS in 2019. CMS is focusing on making a smooth transition to the MIPS. Application of the VBPM on 2018 payments will be expanded to non-physician EP solo practitioners and group practices (e.g., physician assistants, nurse practitioners, and clinical nurse specialists) based on the 2016 performance period.

Medicare Shared Savings Program: The proposed rule includes proposals specific to certain sections of the Shared Savings Program regulations and solicits feedback from stakeholders on the following:

- Adding a measure of Statin Therapy for the Prevention and Treatment of Cardiovascular Disease in the Preventive Health domain of the Shared Savings Program quality measure set to align with PQRS;

- Preserving flexibility to maintain or revert measures to pay for reporting if a measure owner determines the measure no longer aligns with updated clinical practice or causes patient harm;

- Clarifying how PQRS-eligible professionals participating within an ACO meet their PQRS reporting requirements when their ACO satisfactorily reports quality measures; and

- Amending the definition of primary care services to include claims submitted by Electing Teaching Amendment hospitals and exclude claims submitted by Skilled Nursing Facilities.

Misvalued Code Changes for Radiation Therapy: In 2012, CMS identified the codes for radiation therapy as potentially misvalued. The AMA provided recommended values for the new codes issued in 2015, including changes to the assumed number of services that are furnished with the capital equipment.

Based on information provided with the Relative Value Update Committee (RUC) recommendations for the increased use of the equipment, CMS is proposing to change the utilization rate assumption used to determine the per minute cost of the capital equipment by assuming that the equipment is generally used for 35 hours per week (a 70 percent utilization rate) instead of 25 hours per week (a 50 percent utilization rate). CMS is proposing to implement this change over two years. CMS is also seeking comment on additional sources of accurate data regarding how often the machines are in use.

Misvalued Code Changes for Lower Gastrointestinal (GI) Endoscopy Services: CPT revised the lower GI endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that this code set did not allow for accurate reporting of services based upon current medical practice. CMS proposes to value: (1) GI endoscopy codes based on incremental difference methodology; (2) laparoscopic sleeve gastrectomy pursuant to coverage under

the bariatric surgery National Coverage Determination (NCD) in CY 2013; and (3) to redefine and revalue incomplete colonoscopy.

Request for Input on the MACRA: In addition to repealing the SGR formula, MACRA established MIPS and encouraged participation in alternative payment models.

To help with implementation, CMS is requesting input on a number of pieces of MACRA, including the selection of low-volume threshold, the definition of clinical practice improvement activities, and input on how to define a physician-focused payment model, as discussed in section 101(e) of MACRA.

CMS plans on sending out a Request for Information later this year seeking comment on a broader range of issues surrounding MACRA implementation.

Potential Comprehensive Primary Care Initiative (CPCI) Expansion: CMS is requesting public comment on a potential expansion of this multi-payer, patient-centered medical home initiative, which would otherwise end on December 31, 2016.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services: In PAMA, Congress required that providers that order advanced diagnostic imaging services consult with appropriate use criteria via a clinical decision support mechanism. CMS proposes to provide definitions for areas of the statute that require clarification and to establish a process by which the agency will identify clinical areas of priority, specify appropriate use criteria, and lay out a timeline to accomplish these goals.

Part B Payment for Biosimilar Biological Products: In 2010, CMS issued regulations regarding payment for biosimilar biological products using a payment approach specified by the Affordable Care Act (ACA). CMS proposes to update the regulations to clarify that the payment amount for a billing code that describes a biosimilar biological drug product is based on the average sales price (ASP) of all biosimilar biological products that reference a common biological product's license application. In other words, CMS proposed to treat biosimilars as multisource products for the purposes of Part B reimbursement. All biosimilars to a single reference product would share a HCPCS code and be paid on ASP plus 6% of the reference product's ASP.