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September 2, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1600-P
200 Independence Avenue, S.W.
Washington, DC 20201

RE Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015 (CMS-1612-P)

Dear Ms. Tavenner:

On behalf of Johnson & Johnson, we are pleased to submit these comments in response to the 2015 physician fee schedule (PFS) proposed rule, issued in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) on July 11, 2014.

Johnson & Johnson (J&J) is the world's most comprehensive and broadly-based healthcare company, delivering products and services for the consumer, pharmaceutical and medical devices and diagnostics markets. For more than 125 years, have supplied the health system with a broad range of products and have led the way in innovation, beginning with the first antiseptic bandages and sutures. We are continuing this heritage of innovation today, bringing important new pharmaceutical products to market in a range of therapeutic areas, as well as developing important advancements in medical devices and new consumer products.

Our comments below offer the following recommendations:

- Establish a Process for Excluding Some Part B Drug Costs from the Value-Based Payment Modifier
- CMS Should Reference Existing Medical Necessity Requirements in the Context of Expanding the Definition of Colorectal Cancer Screening to Include Anesthesia
- The Process to Establish Values for Moderate Sedation Should Fully Reflect Current Practices
- Maintain Appropriate Flexibility Under the Open Payments Reporting Program for Reporting Continuing Medical Education and Permitting Reporting by Product Category or Therapeutic Area

CMS Should Establish a Process to Identify and Exclude Part B Drug Costs from the Value-Based Payment Modifier (VBPM) When Part D Alternatives Exist

Currently, all Part B costs, including Part B drug and drug administration costs, are included in the total per capita cost measure used for the VBPM, while Part D drug costs are excluded. In the proposed rule, CMS indicates it is not proposing to include Part D data in the total per capita cost measures at this time due to the complexity of the issue. Furthermore, CMS estimates that

“approximately 60 percent of Medicare FFS [fee for service] beneficiaries were enrolled in stand-alone Part D in 2013. Including Part D data would incorrectly indicate higher costs for these beneficiaries compared to others without Part D coverage. Before we are able to propose inclusion of Part D data, we would need to determine an approach to address this issue.” (79 FR 40511)

We agree with CMS that it is important to correctly capture costs across Medicare beneficiaries for purposes of accurately applying the total per capita cost measures. However, as we have explained more fully in our previous comments, excluding Part D data introduces its own inaccuracies. This is because Part B drug costs are included in the measure, and as a result, in those clinical areas where both Part B and Part D drugs are available, physicians treating their patients with Part B drugs appear to have higher costs than their counterparts using Part D drugs.

This is a particular problem for those conditions where drug therapy is an important aspect of treatment, and drugs exist under both Part B and Part D. For example, for rheumatoid arthritis (RA), there are at least 11 disease modifying antirheumatic drugs covered under either Parts B or D. Furthermore, analysis of Medicare claims data indicates that drugs and drug administration comprise between 10 and 17 percent of the total costs to care for RA patients (depending on how long patients have the disease, more recently diagnosed patients have higher total costs and drugs are therefore a smaller percentage).

The impact of this disparate treatment across drugs creates several problems. First, rheumatologists who administer a higher percentage of Part B drugs than their peers will appear to be less efficient. Second, because the total cost measure comprises the bulk of the cost composite for the VBPM calculation, the disparate treatment in this measure has a greater impact than it would if it affected just one measure within the quality of care composite, for example. Third, to the extent physicians respond by taking the risk of shifting patients from Part B to Part D drugs, there could be real impacts on patient quality of care. As just one example, changing treatments for an RA patient when the current therapy is working risks not only moving the patient to a less or even ineffective drug for that patient; but then moving the patient back to the original drug may be complicated by the change in therapies.

We support CMS’ efforts to include the costs of Part D drugs in all of its bundled payment models, but we also recognize the complexity of appropriately including these drugs. In the meantime, however, there are clear and significant distortions that penalize some physicians and may even influence their treatment decisions. Because the Value-Based Modifier becomes effective for many physicians on January 1, 2015, the effect of the payment impacts will soon begin to be felt and will likely have a greater effect on physician behavior. Therefore, it is important that CMS begin to take steps to protect patients from the potentially harmful effects from switching medications due to the financial incentives of the calculation.

We have recommended in our past comments that until CMS is able to include Part D drug costs, it should exclude the costs of Part B drugs/biologics (and their administration costs) from the measure in those instances where there are both Part B and Part D therapies available. CMS could accomplish this by establishing an application process whereby interested parties could request that particular Part B therapies for certain conditions be excluded to avoid distorting the efficiency measurement results. This approach would be straightforward to implement and it would allow CMS to receive input from all interested parties prior to making a decision. It would avoid the complications associated with CMS attempting *a priori* to identify all of the conditions where both Part B and Part D therapies exist.

The current exclusion of Part D drugs while Part B drugs are included clearly disadvantages some physicians by inappropriately making them appear to have higher costs. This type of cost distortion is a concern CMS cites for excluding Part D drugs. We believe the recommendation below offers a straightforward solution that would enable CMS' policies to be more consistent for all physicians and protect Medicare beneficiaries from potentially being switched from treatments that are effectively managing their disease. Furthermore, this approach could extend to other CMS bundled payment approaches that also currently exclude Part D drug costs (e.g., the Medicare Shared Savings Program and the Pioneer Accountable Care Organizations).

Recommendation:

CMS should establish a process through the final rule for 2015 that allows interested parties to request the Part B drugs and their administration costs for specific diseases or conditions be excluded from the calculation of the total cost measure. By permitting requestors to self-identify and explain situations where Part B drugs should be excluded, CMS would not be in the position of identifying all situations where alternative therapies exist. Another option would be to exclude all Part B drugs, or all above a certain threshold.

Under a public nomination process, CMS could establish a deadline and criteria for requestors to describe the circumstances why they propose that Part B drug and administration costs for specific conditions or diseases be excluded. CMS could then describe the request in the annual proposed rule and solicit comments from all interested parties regarding the request. Requestors would be expected to describe the clinical conditions and the alternative therapies covered under Parts B and D (see specific criteria recommendations below). If CMS agrees after considering public comments, it could exclude the costs from the calculation beginning the next calendar year.

This nomination process would be similar to the one CMS uses for approving requests for add-on payments under the inpatient prospective payment system. There, requestors submit applications explaining how their request meets CMS criteria for approval. Similarly, CMS would need to establish criteria to use to evaluate requests to exclude the costs of Part B drugs from the VBPM calculation for specific diseases or conditions.

We believe the following criteria would enable CMS to effectively manage this process:

- Consider specific conditions (eg, rheumatoid arthritis, psoriasis) for exclusion where there are treatment options under both Parts B and D, rather than considering individual drugs for exclusion.

- The clinical goal for the patient is the same across both the Part B and D treatments, and the drug mechanisms of action are the same. Alternatively, if there is a single Part B biologic that has a clinical goal to modify the underlying state of the disease, and patients also take Part D drugs to help manage their disease symptoms, this criterion would not be met.
- It would be appropriate to establish a threshold to ensure the Part B drug (and administration) cost exclusions are only for situations where physicians' VBPM scores are likely to be impacted (eg, at least 5% of their Medicare payments to treat patients with the condition are for Part B drugs, and the Part D drugs are a similar volume).
- Other costs (eg, Part A or B procedures) could also be excluded where they are alternatives to Part D drugs.

We urge CMS to implement such a process in time for applications to be included in the proposed changes to the physician fee schedule for 2016. Otherwise, the distortions described above may begin to impact physician comparisons and even patient care.

Expanding the Definition of Screening Colonoscopies to Include Medically Appropriate Anesthesia Services

We support CMS' efforts to encourage Medicare beneficiaries to seek appropriate colorectal cancer screening services. By waiving the beneficiary deductible and copay for the services of an anesthesia professional during a colonoscopy, CMS seeks to remove barriers to patients seeking this important screening procedure.

CMS points out that until recently, the prevailing standard of care for screening colonoscopies has been moderate sedation provided intravenously by the endoscopist, without resort to separately provided anesthesia (the American Society for Gastrointestinal Endoscopy identifies four levels of sedation for the procedure: minimal; moderate; deep; and general). In the proposed rule, CMS refers to studies that suggest a trend toward greater use of anesthesia professionals. However, this trend has occurred disparately across geographic areas, and is correlated with whether or not payer requirements for the medical necessity of professional anesthesia services are in place. This indicates that payment policies rather than clinical need are driving decisions about anesthesia use.

CMS should clarify that this proposed expanded definition of colorectal cancer screening to include anesthesia services should not be construed to override or preempt existing or planned coverage policies on the appropriate use of these services by its Medicare Administrative Contractors (MACs). For example, Novitas requires that "(u)se of monitored anesthesia care may be considered medically necessary for gastrointestinal endoscopy, bronchoscopy and interventional pain procedures, when there is documentation by the proceduralist or anesthesiologist that specific risk factors or significant medical conditions are present."¹ Noridian has similar requirements.²

In the proposed rule, CMS cited a Journal of the American Medical Association (JAMA) article (a 2012 RAND study) which found that between 2003 and 2009, utilization of anesthesia

¹ Novitas Solutions, Inc, LCD DL27489 - Monitored Anesthesia Care (MAC), May 15, 2012

² Noridian Healthcare Solutions, LCD L24332- Monitored Anesthesia Care (MAC), November 1, 2013

services during gastroenterology procedures increased substantially.³ The article goes on to say “Our data estimate that use of anesthesia services for low-risk patients during gastrointestinal endoscopies may have increased steadily to more than \$1.1 billion per year at the national level. Because anesthesia use is projected to increase further, addressing such potentially discretionary use represents a sizeable target for cost savings. This is particularly true because the number of colonoscopies is likely to increase in the coming years.”

This indicates that while the article found a trend of increasing use of anesthesia services, it did not see indications that the increased use was justified for this level of sedation. The overall conclusions from the JAMA article suggested that much of the spending can be considered potentially discretionary for two main reasons:

1. There was substantial regional variation in the use of anesthesia; and
2. Most anesthesia was provided for low-risk patients

The JAMA article also mentioned “This increased use of anesthesia services has been partly attributed to the adoption of propofol, which by virtue of a short half-life and rapid onset of action is thought to be more convenient and to offer a more consistent level of sedation than regimens previously used, but in the United States should be administered only by persons trained in the administration of general anesthesia.” Another recent published abstract of the analysis of over 2.1 million patients across 11 years demonstrated that sedation during routine colonoscopy and esophagoscopy gastroscopy duodenoscopy (EGD) had excellent safety profile for healthy patients when administered by endoscopists. Utilization of an anesthesia provider did not improve patient safety.⁴

Recently, SEDASYS, a Division of Ethicon US, LLC (part of the Johnson & Johnson Family of Companies), has received market approval for the SEDASYS® Computer-Assisted Personalized Sedation (CAPS) System, a personalized sedation device that provides comprehensive patient monitoring and integrated drug delivery. The SEDASYS® System is an on-label way for trained physician-led (gastroenterologist) teams to safely and effectively deliver minimal-to-moderate sedation with propofol for colonoscopy and EGD procedures in healthy adult patients. The member of the physician-led team who is administering sedation must have training in the management of cardio-respiratory effects of propofol when administered using CAPS systems, and it is restricted for use in settings where an anesthesia professional is immediately available for assistance or consultation. Therefore, the SEDASYS® System provides greater access to propofol for low-risk patients without the requirement of an anesthesiologist to deliver the sedation.

Recommendation:

³ Liu H, Waxman DA, Main R, Mattke S. Utilization of Anesthesia Services during Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009. (2012). JAMA, 307(11):1178-1184. This study was financially supported by Ethicon Endo-Surgery Inc, part of Johnson and Johnson Family of Companies. Ethicon Endo-Surgery Inc had no role in the design and conduct of the study or in the collection, analysis, and interpretation of the data. A draft manuscript was reviewed by Ethicon Endo-Surgery Inc, but the study authors made final decisions regarding the content and study conclusions.

⁴ John J. Vargo, Douglas O. Faigel, Paul Niklewski, James Martin, Jeffrey L. Williams, Jennifer L. Holub; Safety and Risk Factors for Procedural Sedation in the 21st Century: a Review of Over 2 Million Patients From 2000-2011, Volume 77, No. 5S : 2013 GASTROINTESTINAL ENDOSCOPY

As noted above, we support CMS' efforts to improve the rate of beneficiary screening for colorectal cancer. Our request is simply that CMS clarify in the final rule its support for existing MAC coverage determinations or policies that consider the medical appropriateness of anesthesia services provided in conjunction with screening colonoscopies. CMS should also encourage providers to only provide the appropriate level of anesthesia for their patients.

Valuing Services That Include Moderate Sedation As An Inherent Part Of Furnishing The Procedure

We support CMS' goal to improve the payment accuracy for the diagnostic and therapeutic procedures listed in Appendix G of the American Medical Association's Current Procedural Terminology listing. In particular, we support separately valuing the procedure and the sedation for those procedures where moderate sedation is no longer an inherent part of the procedure.

In order to most accurately pay for moderate sedation when it is provided, it will be important to understand the current approaches to delivering moderate sedation and how they differ from each other in terms of resource use. As noted with the introduction of the SEDASYS® System, technology has evolved over time. We would be happy to provide CMS further detail about the relative resources associated with the SEDASYS® System, either directly or through a broader process, such as a survey.

Proposed Changes to the Regulations Implementing Section 6002 of the Affordable Care Act (the "Sunshine Act" or the "Open Payments Program")

Retain a Reporting Exclusion for Continuing Medical Education Speaker Payments

We request that CMS retain a reporting exclusion for payments that applicable manufacturers provide to covered recipients who serve as speakers at continuing medical education (CME) events, but remove the reference to the enumerated accreditation and/or certification organizations listed at § 403.904(g)(1)(i).

We recommend that CMS clarify that payments made to speakers at CME events are excluded from the reporting obligations when (1) the event satisfies the standards of an accrediting organization, (2) the applicable manufacturer does not pay the covered recipient speaker directly, and (3) the applicable manufacturer does not select the covered recipient speaker or provide the CME provider with a distinct, identifiable set of individuals to be considered as speakers. This approach maintains the reporting exclusion where there is independent selection of CME speakers and the CME payments adhere to established standards while avoiding the appearance of CMS endorsing specific accrediting organizations.

Maintain Option for Applicable Manufacturers to Report the Product Category or Therapeutic Area Instead of Marketed Name for a Covered Device

We recommend that CMS maintain the language in the Open Payments final rule issued on February 8, 2013, which provides applicable manufacturers with an option to report the therapeutic area or product category, instead of the marketed name, when reporting an interaction associated with a covered device. Because many medical devices are marketed by their therapeutic area or product category, patients may not be familiar with a particular device's

marketed name. Providing applicable manufacturers with the option of reporting the device's therapeutic area or product category will result in publicly posted data that is generally more meaningful and easier for patients to understand.

We refer CMS to comments submitted by the Advanced Medical Technology Association, the Pharmaceutical Research and Manufacturers of America, and the Biotechnology Industry Organization for a more detailed discussion of the relevant issues associated with CMS's proposed removal of (i) the CME exclusion and (ii) the option for reporting therapeutic area or product category for covered devices.

J&J appreciates the opportunity to submit our comments and recommendations to CMS. We also appreciate the past opportunities for working with you and your staff to ensure the accuracy and fairness of Medicare's payments to physicians, and look forward to continuing to do so.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Phillips", written in a cursive style.

Steve Phillips

Senior Director, Health Policy
Worldwide Government Affairs & Policy
Johnson & Johnson