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August 27, 2014

VIA OVERNIGHT MAIL

Ms. Marilyn Tavenner
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed CY 2015 Medicare Payment Policies under the Physician Fee Schedule (CMS-1612-P)

Dear Ms. Tavenner:

Stryker appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed calendar year (CY) 2015 Medicare physician fee schedule (MPFS) rule (Proposed Rule).

Stryker is one of the world's leading medical technology companies and together with our customers, we are driven to make healthcare better. Stryker is committed to bringing the best possible healthcare solutions to patients, providers, and Medicare. The Company offers a diverse array of innovative medical technologies, including reconstructive, medical and surgical, and neurotechnology and spine products to help people lead more active and more satisfying lives.

Our comments on the proposed CY 2015 MPFS rule are summarized below and discussed in greater detail in the following sections:

- **Deep SGR Cut Needs To Be Averted**. Although CMS proposes a zero update for the first three months of 2015, providers still face the prospects of a more than 20 percent across-the-board cut in MPFS rates effective April 1, 2015. Such cuts, resulting from the statutory sustainable growth rate (SGR) formula, would threaten the ability of physicians to continue to furnish high-quality services to Medicare beneficiaries. While a long-term solution is needed, it is imperative that CMS explore all administrative options at its disposal for avoiding such a dramatic cut and ensuring appropriate Medicare payment for physician services for all of 2015.

- **Promoting Transparency in the Valuation of RVUs.** Stryker commends CMS for its proposal to ensure that the public has a meaningful comment opportunity on proposed changes to values for existing medical procedures. At the same time, we agree that

CMS's proposed new timeline should not in any way impede beneficiary access to new medical procedures technologies. An expedited process, including the use of interim relative value units (RVUs) as necessary, should be maintained to provide an administratively simple mechanism for valuing new codes.

- **Potential Use of OPPS Data to Establish Practice Expense (PE) RVUs.** We continue to caution CMS about the inapplicability of hospital outpatient data to the physician office setting, particularly since Medicare outpatient prospective payment system (OPPS) rates have been skewed by charge compression. CMS should not assume that OPPS rates are necessarily more accurate than established MPFS rates. While we agree that CMS could flag for further review those MPFS values that exceed OPPS rates, CMS should use a deliberate, data-driven process to individually review and, if appropriate, revise relative values.

- **Updates to the Physician Quality Reporting System (PQRS).** Stryker supports total knee and hip replacement measures that promote high-quality care for Medicare beneficiaries. We therefore request that CMS ensure that proposed revisions to the Total Knee Replacement Measure Group are targeted to promote quality patient care, and that any expansion of reporting on Physician Compare ensures that data presented to the public is understandable to patients and fair to physicians.

- **Physician Payment Sunshine Act Proposals.** We urge CMS not to adopt its proposed changes to the Physician Payment Sunshine Act regulations that would remove the continuing education exemption and require the reporting of the marketed name of covered and non-covered devices and medical supplies.

Our detailed comments follow.

I. Deep SGR Cut Needs To Be Averted

Under temporary legislative authority provided by the Protecting Access to Medicare Act of 2014 (PAMA), CMS is proposing a zero percent update for PFS services furnished on or after January 1, 2015 and on or before March 31, 2015 (which results in a slight decrease in the conversion factor due to a budget neutrality adjustment). The PAMA authority expires on March 31, 2015, and the statutory SGR formula would apply effective April 1, 2015 unless new legislation is enacted. CMS has estimated that the SGR formula could result in a cut of 20.9 percent.

This drastic cut would threaten the ability of physicians to continue to furnish high-quality services to Medicare beneficiaries. We encourage CMS to continue to work with Congress, the provider community, and other stakeholders to find a long-term solution to the SGR formula that provides a stable reimbursement mechanism for physicians. In the meantime, however, it is

imperative that CMS explore all administrative options at its disposal for avoiding such a dramatic cut and ensuring appropriate Medicare payment for physician services for all of 2015.

II. Promoting Transparency in Valuation of Procedures

In previous comment letters, Stryker has expressed our concerns about CMS using interim final rules to announce dramatic reductions in the values (and consequently the reimbursement) for established medical procedures under the Agency's potentially "misvalued" code initiative. While the use of interim values is an important option to accelerate beneficiary access to new medical procedures and technologies, it is disruptive to physician practices and patients for CMS to institute deep payment cuts to established procedures in an interim final rule mere weeks before cuts go into effect. We were particularly concerned about CMS's use of the CY 2014 interim final rule to adopt significant cuts in work RVUs for primary total hip and total knee arthroplasty procedures, since it could negatively impact beneficiary access to these important procedures, and because the Agency provided insufficient notice to affected physicians and their patients. We recommended that CMS provide stakeholders with an open and transparent process to consider revisions impacting established procedures.

Stryker therefore commends CMS for its efforts to ensure that the public has a meaningful comment opportunity on proposed changes to values for existing medical procedures. At the same time, we agree that such safeguards for existing procedures should not in any way impede beneficiary access to new medical procedures technologies. An expedited process, including the use of interim RVUs as necessary, should be maintained to provide an administratively simple mechanism for valuing new codes. We also encourage CMS to work with the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) to more closely align calendars for consideration of new codes to minimize delays in establishing values for new and revised codes, and to minimize the use of administratively-burdensome G-codes to represent codes that are being revised or deleted.

III. Potential Use of OPPS Data to Establish PE RVUs

In the CY 2014 proposed rule, CMS proposed to reduce the MPFS nonfacility PE RVUs for more than 200 codes where Medicare pays more for services furnished in a physician's office than in an outpatient hospital department or ambulatory surgical center. Stryker objected to the 2014 proposal on numerous policy grounds, and we were pleased that CMS agreed and did not finalize this policy. In the current CY 2015 Proposed Rule, CMS acknowledged that it was "persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that that PFS payment rates are based on accurate cost assumptions."

Nevertheless, CMS apparently still believes "that there are a various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated." CMS therefore seeks to exercise its authority under the PAMA to use alternative approaches to establish PE RVUs, including using hospital outpatient cost data. While CMS indicates that it would be taking a different approach than presented in the CY 2014 proposed MPFS rule, CMS suggests that it may use hospital outpatient data to validate or set relative resource cost assumptions within the PFS PE methodology.

We continue to caution CMS about the inapplicability of hospital outpatient data to the physician office setting. CMS itself has acknowledged in recent years that OPPS rates have been skewed by charge compression – or the hospital practice of applying a lower charge markup to higher cost services and a higher charge markup to lower cost services, which has the result of undervaluing high-cost items and overvaluing low-cost items. CMS has taken a series of steps to create additional hospital cost centers to mitigate charge compression and improve the accuracy of OPPS rates, but these initiatives are still being implemented. We therefore are concerned about CMS assumptions that OPPS rates are necessarily more accurate than established MPFS rates across-the-board. While we agree that CMS could flag for further review those MPFS values that exceed OPPS rates, CMS should use a deliberate, data-driven process to individually review and, if appropriate, revise (up or down) PFS relative values.

IV. Updates to the Physician Quality Reporting System (PQRS)

CMS proposes to update the measures and measure sets in the PQRS. Among other things, CMS is proposing to update its measures groups to increase the minimum number of measures to six measures, which would necessitate the addition of two measures to the Total Knee Replacement Measure Group for 2015 and beyond: (1) Documentation of Current Medications in the Medical Record, and (2) Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention. Stryker supports total knee and hip replacement measures that promote high-quality care for Medicare beneficiaries. Unlike the other measures in this measure group, however, these measures are not developed by American Association of Hip and Knee Surgeons (AAHKS). We therefore recommend that CMS ensure that the clinical experts agree that these measures are relevant to quality patient care – which is far more important than complying with an arbitrary minimum measure standard. In addition, we urge CMS to move slowly with implementing all new measures and work with the specialty societies and physicians so they know when grading starts and how this will impact payment

CMS also is considering publishing on Physician Compare a Total Knee Replacement composite group, beginning in 2016. We generally support making such data available to the public to promote quality of care, although we would request additional information on how the data would be presented to the public to be both understandable and relevant to patients and fair to physicians.

V. Proposed Revisions to the Physician Payment Sunshine Act

CMS is proposing a series of changes to the regulations implementing the Physician Payment Sunshine Act/Open Payments program. Notably, CMS proposes removing the current reporting exclusion for payments or other transfers of value provided as compensation for speaking at a continuing education program. The current exclusion requires three conditions to be met:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations: the Accreditation Council for Continuing Medical Education (ACCME); the American Academy of Family Physicians (AAFP); the American Dental Association's Continuing Education Recognition Program (ADA CERP); the American Medical Association (AMA); or the American Osteopathic Association (AOA).

- The applicable manufacturer does not pay the covered recipient speaker directly.

- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

CMS expresses concerns that its enumeration of organizations amounts to an apparent endorsement or support to organizations sponsoring continuing education events. CMS also contends that such payments would be covered by a separate provision that excludes indirect payments or other transfers of value where the applicable manufacturer is "unaware" of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

We object to CMS's proposal to remove the continuing education exemption, since it would remove an important bright-line test that enables support of valuable educational activities. The less precise "unaware" standard could lead to confusion about reporting obligations just as the new reporting framework is getting underway. If CMS is concerned about the impression made by enumerating accrediting organizations, CMS should maintain a more general accreditation standard for such events, rather than discouraging participation in ongoing medical education that is critical to advanced medical technologies.

Likewise, we object to CMS's proposal to require the reporting of the *marketed name of covered and non-covered* devices and medical supplies – rather than allowing the manufacturer to report the general therapeutic area or product category. CMS already considered this issue in last year's final rule, confirming the need for "greater flexibility in reporting the product name, particularly for devices where the product name is less recognizable to consumers." CMS also rightfully acknowledged that reporting the device or medical supply therapeutic area or product

category is appropriate because "a single product may actually be comprised of multiple devices," while the names of drugs and biologicals are more readily available to consumers since they are often listed on a prescription.[1] Moreover, CMS already specifically considered this requirement with regard to non-covered products, and concisely stated that "we do not believe applicable manufacturers should be required to report the name of associated non-covered products, since this may be misleading to the consumers and would provide information that is beyond the goal of the statute."[2]

The Proposed Rule would upend settled policy and impose a significant administrative burden on manufacturers with extensive brand-name product lines at a time when extensive internal reporting procedures and policies have already been developed – in the name of the making "data fields consistent within the system." We urge CMS not to finalize this proposal.

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Thank you for your consideration of our comments, which are intended to promote Medicare beneficiary access to important medical treatment options in the physician office setting.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Eric Rugo
Vice President Government Affairs and Health Policy

1 78 Fed. Reg. 9457, 9475 (Feb. 8, 2013).

2 *Id* at 9474.