PRIVATE PRACTICE SECTION, APTA

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American Physical Therapy Association

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Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
9500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-5516-P

Dear Acting Administrator Slavitt:

The Private Practice Section (PPS) of the American Physical Therapy Association (APTA) respectfully submits these comments on CMS-5516-P the CMS proposed initiative to support better and more efficient care for beneficiaries undergoing hip and knee replacements (also called lower extremity joint replacements or LEJR). This model, called the Comprehensive Care for Joint Replacement Model, would test bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial hospitalization through recovery.

The PPS is the Private Practice Section of the 90,000 member American Physical Therapy Association. Our 4,300 members are physical therapists who are primarily the owners or partners in independent private practice across the nation. Their patient-focused clinics are conveniently located throughout the community where therapists and patients form a bond over the course of treatment. Therapists regularly communicate with other appropriate members of their patient's health care team.

Hip and knee replacements are the most common inpatient surgery for Medicare beneficiaries and can require lengthy recovery and rehabilitation periods. In 2013, there were more than 400,000 inpatient primary procedures costing more than $7 billion for hospitalization alone.

CMS indicates that the quality and cost of care for these hip and knee replacement surgeries still varies greatly. For instance, the rate of complications like infections or implant failures after surgery can be more than three times higher at some facilities than others, which can lead to hospital readmissions and prolonged recoveries. And the average Medicare expenditure for surgery, hospitalization, and recovery ranges from $16,500 to $33,000 across geographic areas.

This variation is due partly to the way Medicare beneficiaries receive care. CMS says incentives to coordinate the whole episode of care – from surgery to recovery – are not strong enough, and a patient's health can suffer as a result. The Agency believes when care is approached without regard to "the big picture," there is a risk of missing crucial information or not coordinating across different care settings. It is believed that this approach leads to more post-surgery complications, high readmission rates, and inconsistent costs.

PPS Comment: *PPS agrees that there is excessive variation in quality and cost, but we are not convinced the demonstration as proposed contains all the elements required and thus we believe it will fall short of the intended goal while being overly burdensome to the providers. Excessive control is placed in the hands of the hospitals and participating hospitals have insufficient incentive to ensure inclusion of the highest quality independent clinicians and private practitioners who they view as competitors to the hospitals' physical therapy departments. Simultaneously, PPS sees insufficient safeguards to ensure that the patient's freedom of choice is protected.*

While addressing fragmentation of care by focusing on coordinated, patient-centered care is an admirable goal, PPS believes the proposed model does not include enough safeguards to substantially improve the care experience for the many and growing numbers of Medicare beneficiaries who receive joint replacements. Placing the patient's successful surgery and recovery as the top priority of the health care system requires a more robust emphasis on the beneficiary's functional outcomes, including requiring functional status measurement through the use of existing tools that employ rigorous psychometrics and whose resulting data can be risk-adjusted.

Mechanics of the Program

- Under this proposed model, the hospital in which the hip or knee replacement takes place would be accountable for the costs and quality of care from the time of the surgery through 90 days after, which is referred to as an "episode" of care.

- Depending on the hospital's quality and cost performance during the episode, the hospital would either earn a financial reward or be required to repay Medicare for a portion of the costs. This payment would give hospitals an incentive to work with physicians, home health agencies, nursing facilities and other providers/professionals to ensure beneficiaries receive the coordinated care they need with the goal of reducing avoidable complications including rehospitalization. Hospitals would have additional tools – such as spending and utilization data and sharing of best practices - to improve the effectiveness of care coordination.

PPS Comment: *PPS believes excessive financial and programmatic control is embedded in the hospitals and the incentives and safeguards are insufficient to accomplish meaningful coordination of care and optimal patient outcome.*

The proposed rule calls for beneficiaries to retain their freedom of choice to choose services and providers. Physicians and hospitals would be expected to continue to meet current standards required by the Medicare program. All existing safeguards to protect beneficiaries and patients would remain in place. If a beneficiary believes that his or her care is adversely affected, he or she is advised to call 1-800-MEDICARE or contact their state's Quality Improvement Organization by going to http://www.qioprogram.org/contact-zones. The proposed rule also describes additional monitoring of claims data from participant hospitals to ensure that hospitals continue to provide all necessary services.

PPS Comment: *PPS commends the Agency for attempting to address the patient's freedom of choice but we are skeptical that the mere mention of this choice will be sufficient to overcome the bias that is inherent in the hospital system to resist referring out-of-system to independent rehabilitation professionals who may be more cost-effective and achieve higher functional*

outcomes with total knee and total hip patients. PPS believes that greater emphasis must be placed on ensuring the inclusion of professionals and providers who have demonstrated, or can demonstrate effectiveness and efficiency of care. At minimum, beneficiaries should be notified in writing of the providers from whom they can choose to receive their rehabilitation therapy.

Moreover, PPS believes that the references to quality and even "outcomes" throughout the proposal are less than rigorous. The reference to measurement in the entire proposal is quite hospital-centric and there is very little mention of patient functional status, let alone the measurement of same by the use of measurement tools that employ strong psychometrics.

Measuring Quality

Even though the proposed rule does include considerable detail describing how quality is to be measured, the quality references are almost exclusively hospital-focused as opposed to patient-centric. To wit:

- *Hospital-level 30-day, all-cause RSRR following elective primary THA and/or TKA (NQF #1551),*
- *Hospital-level RSCR following elective primary THA and/or TKA (NQF #1550),*
- *HCAHPS survey (NQF #1661), and*
- *Voluntary THA/TKA data submission on patient-reported outcome measure.*

In addition, the proposed rule indicates the demonstration project will enable hospitals to have additional tools --such as spending and utilization data and sharing of best practices -- to improve the effectiveness of care coordination. However, the meaning of "sharing of best practices" is not clear; nor is it understood how such information will be constituted or upon what it will be based. PPS cautions that the proposal tends to rely too much on "utilization data" to analyze effectiveness of the program and such focus will guarantee that the important metric will be cost and not quality.

Unfortunately, what is clear in the proposed model is the hospital control of the program, including control of the money. This is found throughout the proposed rule in references such as "the hospital would earn" or "the hospital would be paid." This reminds us of the age-old "golden rule" – the party who has the gold, makes the rule. PPS urges CMS to pursue a more balanced model that achieves shared control of the finances and programmatic features.

Measuring Outcomes

In the proposed rule, CMS reiterates its goal of moving toward outcome measures that assess patient reported outcomes and the Agency reports that it has begun development of a measure to assess improvement in patient-reported outcomes following THA/TKA procedures. The measure will assess change between pre- and post-operative patient-reported outcomes for THA and TKA separately or as a composite measure for both procedures. The measure will use one or more of the following patient-reported outcome instruments (or validated subscales or abbreviated versions of these instruments) to calculate the measure score: the Patient Reported Outcomes Measurement Information Systems (PROMIS)-Global or the Veterans Rand 12 Item Health Survey (VR-12), and the Hip dysfunction and Osteoarthritis Outcome Score/Knee injury and Osteoarthritis Outcome Score (HOOS/KOOS) instruments to measure pre- and postoperative improvement or both.

CMS acknowledges that patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way and are also influenced by a range of improvements in care. [1,2,3] The Agency also emphasizes that patient-reported outcomes with respect to improved function and reduced pain are the most meaningful outcome metric to assess in these patients.

CMS states that The Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty is currently under development. [CMS] specifically chose to focus on THA/TKA procedures since THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way and are also influenced by a range of improvements in care. [1,2,3] Patient-reported outcomes will be assessed separately for THA and TKA procedures, though these results may be combined into a single composite measure for reporting. Therefore, [CMS] will refer to a single measure, but acknowledge the possibility of two measures, one for THA patients and one for TKA patients.

CMS also expresses the need to access a nationally representative sample of THA and TKA inpatient surgical procedure patient-reported outcome data set that is also consistently collected at the hospital-level and contains risk variables identified by orthopedists. The rationale for requesting access to a national THA and TKA inpatient surgical procedures patient-reported data source are twofold: (1) A national data source would provide us with hospital-level data representative of the total number of THA and TKA procedures performed in hospitals, as well as representative data on hospital-level case-mix; and (2) access to a national THA and TKA inpatient surgical procedures patient-reported data source would allow us to assess and identify a set of parsimonious data elements that will minimize the data collection burden by patients, physicians and hospitals. [CMS] believes access to such data would allow for completion and testing of the current measure under development that can be appropriately used for nationwide hospital performance evaluation.

PPS Comment: *It may indeed be true that current data sources for THA and TKA inpatient surgical procedures are insufficient at this time to enable assessment of performance of hospitals and physicians. But PPS would urge the Agency to avoid placing excessive emphasis on hospital and physician services and place an equal emphasis on rehabilitation therapy and functional outcomes experienced by the patients. PPS notes that numerous such measures possessing robust psychometrics are available and in use across the country and many are even risk-adjusted. In other words, the Agency's professed intention to spend a considerable length of time evaluating the reliability of the patient-reported outcome measures and examining validity of the patient-reported outcome measure upon finalization of the risk adjustment model via potential testing methods such as face validity testing with national experts, comparing the measure results to similar results based on other data sources if feasible, etc." has already been accomplished as is evidenced by the literature. It is neither necessary nor prudent for CMS to embark upon the development of more measurement instruments. At minimum, CMS should recognize measures that have been endorsed by the National Quality Forum – particularly functional status measures -- and are in use in other Medicare programs including the Physician Quality Reporting System (PQRS).*

In addition, PPS asserts that collection of important data on a voluntary basis is not ideal particularly when it comes to assessing functional outcomes of beneficiaries. The collection and submission of patient-reported functional outcomes measures should be compulsory (not voluntary) and it should be standardized.

Moreover, these measures have been found to be meaningful to patients and clinicians, and possess performance characteristics (robust psychometrics) such as reliability, responsiveness and validity. Best of all these measures are not perceived as burdensome by patients or providers.

Regrettably, CMS seems unaware of the myriad evidence-based and psychometrically sound measures proven to accurately measure functional status and functional outcomes available in the literature and in use in many of our private physical therapy practices on a regular basis.[4-21] *Some of these outcomes processes are even risk-adjusted.* [6-12] *Nevertheless, CMS indicates it has embarked on the development of an outcome metric for these total joint procedures. PPS advises against the development of a new measure dedicated to THA/TKA, and instead encourages CMS to employ evidence-based and scientifically defensible measures already in clinical use.*

The metric described in the proposal will be a Hospital-Level Performance Measure(s) of Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty. The most important metric – the ultimate functional outcome resulting from the completion of physical therapy – should have equal or greater representation in the bundled payment initiative.

Finally, PPS notes that the Agency's belief that as the measure it intends to create continues to undergo development that the list of data elements may be simplified. Again, this has already been accomplished in the public and private sector and pursuit of a redundant process is imprudent use of government resources.

Collaboration with Providers and Suppliers

But while the initiative does provide the primary financial incentive to the hospital, CMS does explicitly state its belief "that participant hospitals may wish to enter into financial arrangements with providers and suppliers caring for beneficiaries in CCJR episodes in order to align the financial incentives of those providers and suppliers with the model goals of improving quality and efficiency for LEJR episodes. For example, given that the proposed episode duration is 90 days following discharge from the anchor hospital stay and the episodes are broadly defined, many providers and suppliers other than the participant hospital will furnish related services to beneficiaries during episodes. Those providers and suppliers may include physicians, physician group practices, skilled nursing facilities (SNFs), home health agencies (HHAs), inpatient rehabilitation facilities (IRFs), long term care hospitals (LTCHs), outpatient therapy providers, and others. [CMS] expects that participant hospitals will identify key providers and suppliers for CCJR beneficiaries in their communities and then establish close partnerships with them to assist the hospital in redesigning care for LEJR episodes to improve quality and efficiency, coordinating and managing care for beneficiaries, monitoring episode performance, and refining care pathways. These providers and suppliers may invest substantial time and other resources in these activities, yet they would neither be the direct recipients of any reconciliation payments (to the hospital) from Medicare, nor directly responsible for repaying Medicare for excess episode spending. Therefore, we believe it is possible that a participant hospital that may receive a reconciliation payment from

Medicare or may need to repay Medicare may want to enter into financial arrangements with other providers and suppliers to share risks and rewards under CCJR."

CMS also submits that CCJR collaborators should have a role in the participant hospital's episode spending or quality performance. As a result, the Agency proposes "that the CCJR collaborator would directly furnish related items or services to a CCJR beneficiary during the episode and/or specifically participate in CCJR model LEJR episode care redesign activities, such as attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries' clinical courses; developing episode analytics; or preparing reports of episode performance, under the direction of the participant hospital or another CCJR collaborator that directly furnishes related items and services to CCJR beneficiaries."

But later in the rule, the Agency proposes "a limit on Gainsharing Payments to physician or nonphysician CCJR collaborators, as well as to physician group practices, related to Physician Fee Schedule (PFS) payments for services furnished to CCJR beneficiaries. This means that, in addition to playing a role in the participant hospital's episode spending or quality performance, physician, nonphysician, and physician group practice CCJR collaborators must directly furnish services to CCJR beneficiaries in order to receive a Gainsharing Payment as result of their financial arrangement with the participant hospital."

Any such arrangement between a participant hospital and a CCJR collaborator shall be termed a "CCJR Sharing Arrangement" or a "Participation Agreement" and that the terms of each such Arrangement must be set forth in a written agreement between the participant hospital and the CCJR collaborator.

The CCJR Sharing Arrangements between participant hospitals and CCJR collaborators must be solely related to the contributions of the CCJR collaborators to care redesign that achieve quality and efficiency improvements under this model for CCJR beneficiaries. All Gainsharing Payments (aka "Alignment Payments") between participant hospitals and CCJR collaborators resulting from these arrangements must be auditable by HHS to ensure their financial and programmatic integrity. Moreover, the Payments must be actually and proportionally related to the care of beneficiaries in a CCJR episode, and the CCJR collaborator must be contributing to the care redesign strategies of the participant hospital.

PPS Comment: *PPS generally finds these collaboration guidelines acceptable but their effectiveness will depend on robust enforcement which is not discussed in the proposal. In addition, as mentioned previously, beneficiaries should be notified in writing and in a timely manner that they have the freedom to choose their providers for their rehabilitative recovery.*

Beneficiary Choice

In the proposed rule, the Agency emphasizes that the CCJR model does not affect the beneficiary's freedom of choice to obtain health services from any individual or organization qualified to participate in the Medicare program. However, eligible beneficiaries who choose to receive services from a participant hospital would not have the option to opt out of inclusion in the CCJR model. Although the proposed model allows hospitals to enter into risk-sharing arrangements with certain other providers and these hospitals may recommended those providers to the beneficiary, hospitals may not prevent or restrict beneficiaries to any list of preferred or recommended providers.

Many controls exist under Medicare to ensure beneficiary access and quality and CMS has proposed to use its existing authority, if necessary, to audit participant hospitals if claims analysis indicates an inappropriate change in delivered services. This measure is intended to ensure that participant hospitals do not stint on care or avoid complex, high cost cases by referring them to nearby facilities or specialty referral centers. CMS also proposes to require providers to supply beneficiaries with written information regarding the design and implications of the CCJR model as well as their rights under Medicare, including their right to use their provider of choice.

PPS Comment: *PPS agrees with the beneficiary choice provisions and urges that the advanced written notification regarding the design and implications of the CCJR model as well as beneficiary rights under Medicare, including their right to use their provider of choice, be vigorously enforced.*

Beneficiary Incentives

The Agency also believes hospitals caring for CCJR beneficiaries may want to offer beneficiary incentives to encourage beneficiary adherence to recommended treatment and active patient engagement in recovery. But the proposed rule requires that such incentives be closely related to the provision of high quality care during the episode and advance a clinical goal for a CCJR beneficiary, and should not serve as inducements to beneficiaries to seek care from the participant hospital or other specific suppliers and providers.

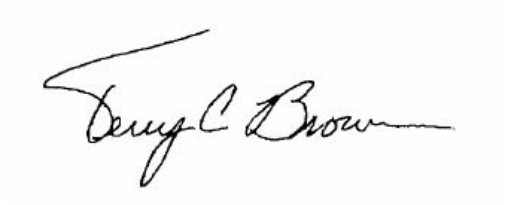
The Agency professes its belief that the hospital is better suited than other providers and suppliers to provide beneficiary incentives. Thus, CMS proposes to include in the CCJR model certain in-kind patient engagement incentives to the beneficiary, subject to the following conditions:

- The incentive must be provided during CCJR episode of care.
- There must be a reasonable connection between the item or service and the beneficiary's medical care.
- The item or service must be a preventive care item or service or an item or service that advances a clinical goal for a CCJR beneficiary, including the following:
    - Increasing the beneficiary's engagement in the management of his or her own health care;
    - adherence to a treatment or drug regimen;
    - adherence to a follow-up care plan;
    - reduction of readmissions and complications resulting from LEJR procedures; and
    - management of chronic diseases and conditions that may be affected by the LEJR procedure.
- Items of technology comply with certain safeguards regarding value.
- The hospital must maintain contemporaneous documentation of the incentives provided to beneficiaries for a period of 10 years.
- The cost of the incentives is not shifted to another federal health care program.

PPS Comment: *PPS believes it is paramount that hospitals not be allowed to offer incentives to beneficiaries that can induce patients to obtain their rehabilitation therapy from the participant hospital or other specific suppliers and providers.*

PPS thanks the Agency for the opportunity to provide these comments on the proposed rule for the bundled payment initiative known as the Comprehensive Care for Joint Replacement Model. PPS is committed to continue its cooperation and collaboration with CMS and we look forward to more opportunities to partner with the agency in pursuit of meaningful and effective innovation in the Medicare program.

Sincerely,



Terence C. Brown, PT, DPT
President, PPS/APTA

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