



September 8, 2015

DELIVERED ELECTRONICALLY

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2390-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS–5516–P Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services

Dear Acting Administrator Slavitt:

The Coalition to Preserve Rehabilitation (CPR) appreciates the opportunity to comment on the above-referenced proposed rule.¹ As this proposed rule also references the Bundled Payments for Care Improvement Initiative (BPCI), this comment letter incorporates by reference CPR’s previous comment letters on the BPCI, submitted June 23 and August 20. CPR is a coalition of national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities and chronic conditions may regain and/or maintain their maximum level of health and independent function.

While many of the undersigned organizations have constituents who are not directly affected by the Comprehensive Care for Joint Replacement Payment (CCJR) model, the undersigned organizations are concerned about the potentially precedent-setting nature of this proposed rule for other patient populations. Indeed, we are concerned about the very concept of defining appropriate care based on a particular diagnosis or treatment, as is proposed here for joint replacements. This sort of “rule of thumb” has long been found to conflict with Due Process, Medicare law and policy, which require an individualized assessment of each beneficiary’s need.

¹ *Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services*; Proposed Rule, 80 Fed. Reg. 41,198 (July 14, 2015). Available at: <http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17190.pdf>.

Medicare PAC Payment Reform Requires Serious Deliberation and Reliable Data

All Medicare post-acute care (PAC) reforms that the Centers for Medicare and Medicaid Services (CMS) considers, including the Comprehensive Care for Joint Replacement Payment (CCJR) model, should, first and foremost, preserve access to quality rehabilitation services provided at the appropriate level of intensity, in the right setting, and at the right time to meet the individual needs of Medicare beneficiaries. This is, of course, much easier said than done. Meeting this challenge, while making Medicare PAC payment policy more efficient, requires serious deliberation and should be based on reliable data that is comparable from one PAC setting to another. Uniform and current data need to be collected across a variety of PAC settings with a major emphasis on appropriate quality standards and risk adjustment to protect patients against underservice. Implementation of the IMPACT Act now serves this data collection purpose.

CPR favors payment and delivery models that are based on sound evidence with fully developed quality measures and risk-adjusters so that any savings are achieved through genuine efficiencies, not achieved by stinting on patient care. Unfortunately, a “bundled” PAC payment system that includes these critical beneficiary protections does not currently exist and, we expect, will take several years to develop, adequately test, and validate. This is why we support refraining from either regulating or legislating “site-neutral” PAC payments, or taking other PAC reform actions until data is collected and analyzed under the authorities enacted in the IMPACT Act.

This data can be used to develop a uniform quality assessment instrument to measure outcomes across PAC settings. Such a tool would be invaluable to developing and enacting PAC reforms that do not compromise patient care. This is a critical step in both adopting appropriate—and sufficiently granular—quality metrics to ensure PAC patients under a bundled Medicare payment system achieve good patient outcomes and risk adjusters that accurately capture the unique needs of individual patients.

Until these and other patient protections are in place, we do not support regulating or legislating PAC reforms that bundle episodes of care, impose financial incentives to treat patients in the least intensive setting, or otherwise limit rehabilitation benefits under the Medicare program. It is simply too risky to Medicare beneficiaries to implement PAC bundling or related reforms prematurely.

Therefore, we request that CMS take sufficient time to collect data under the IMPACT Act’s provisions, before adopting this proposed rule and future rules. Otherwise, a short-term, underdeveloped, approach to PAC reform will result that may negatively impact the recovery and rehabilitation of some of Medicare’s most vulnerable beneficiaries. That being said, we support the retrospective, PAC related surveys, site visits, and focus groups meant to evaluate the effects of the CCJR model on PAC providers.²

Definition of “Episode of Care”

While we strongly oppose the concept of the proposed rule, if it is to proceed, CPR recommends that CMS at least allow for flexibility in defining the length of the episode covered by the CCJR bundle. Further to the need for individualized assessments, we note that these patients are far more than “joint replacements.” They include individuals with brain injuries, some spinal cord injury patients, those with multiple traumas, medically complex and ventilator patients currently in inpatient rehabilitation hospitals (IRHs) and long-term care hospitals (LTCHs), and others.

² *Id.* at 41,298.

The definition of the episode of care, particularly for post-acute care episodes, should be flexible and perhaps even condition-specific. Either way, it should be long enough to incentivize providers to provide timely care and not simply “run out the clock” until providers can bill separately for services covered under Medicare Part B.

CPR also recommends that PAC episodes be based on standardized assessment data across PAC settings as well as discharge diagnostic and clinical information, which is not the case at this time. The Improving Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113-185) would provide at least some of the standardized data necessary to help develop clear episode recognition and definition. Until such time as patients with brain injuries, spinal cord injuries, multiple amputations and similarly serious conditions can be assured appropriate care post injury or illness, CMS should exempt these subpopulations of patients from bundled payment systems. CPR supports CMS’ exclusion of those with acute disease diagnoses, namely those with severe head injury, from the bundle.³

Qualifications of the Bundle-Holder

We also have serious reservations with the proposal to permit acute care hospitals to serve as the holder of the bundle for not only hospital care associated with lower extremity joint replacements but also all related post-acute and sub-acute care for 90 days following discharge. Regardless of their ability to assume the risk, there are strong incentives in the CCJR model for entities with little direct knowledge of rehabilitation to divert patients to the least costly PAC setting, as long as these patients are not readmitted to the acute care hospital, which comes with financial penalties. In fact, one stated goal of the CCJR model is to increase utilization of home health services and outpatient therapy, and reduced utilization of IRFs and skilled nursing facilities (SNFs) post-joint replacement.⁴ The CCJR model also encourages hospitals to recommend PAC settings that are “clinically appropriate” and “of the lowest acuity.”⁵ Current law requires the CMS to pilot test a concept known as the Continuing Care Hospital (CCH),⁶ where the PAC bundle is held by a combination of post-acute care providers (i.e., LTACH, IRF and hospital-based SNF). This would, at least, place the bundle in the hands of providers who understand rehabilitation and these patients’ needs.

CPR recommends that the bundle-holder have the appropriate knowledge of the clinical needs of Medicare beneficiaries who require rehabilitation and PAC services, as this is a heterogeneous population, particularly with regard to PAC services. Bundle-holders should also have an adequate understanding of the differences among settings of care, particularly the differences between inpatient hospital rehabilitation and skilled nursing. Without proper quality metrics to ensure beneficiaries are protected and criteria to ensure the bundle-holder is capable of administering the bundle and its associated services, access to services for beneficiaries could be jeopardized.

CPR believes any entity qualified to serve as the bundle-holder must meet specific criteria, including:

- The requisite clinical staff and expertise overall and for each condition included in the program;
- Systems in place to include rehabilitation physicians and extenders early in the discharge planning process to help in identifying the proper trajectory of care for patients;

³ *Id.* at 41,215, 41,308.

⁴ *Id.* at 41,254.

⁵ *Id.* at 41,268.

⁶ Inexplicably, CMS has not yet pursued the mandated CCH pilot program.

- The ability to deliver, or contract for, the entire bundle of services to be rendered, including clear statements of the capacity to provide all levels of rehabilitation services, including IRF services.
- Clinical pathways and effective discharge planning capacities;
- The ability to manage transitions or handoffs from one setting to another when necessary (e.g. entry, transitions, and discharge);
- Interoperable health information technology and decision support systems that seek to meet or meet HHS/CMS EHR standards and which communicates between acute and post-acute care providers;
- The ability to monitor patient clinical status and coordinate medication management as patients progress across acute and post-acute settings;
- The ability to track quality indicators and patient outcomes across an array of services and settings;
- The ability to manage medical complications and assume risk for readmissions;
- The ability to coordinate with other community services to foster the patient’s independence, including coordination with providers of durable medical equipment, prosthetics, orthotics, and supplies; and,
- The ability to care for all types of patients including intense medical rehabilitation patients and medically complex patients.

The Bundle-Holder’s Assumption of Risk

Any bundle-holder must be truly able to assume the risk of holding this bundled payment while providing services to a beneficiary across a 90-day episode of care. Financial solvency, transparency, appropriate governance, accountability, and related standards should be more explicitly adopted in the regulation to ensure that bundle-holders have the capacity to provide consistent and reliable care, even to outlier patients. Such standards are readily available and well validated through a number of accreditation organizations that specialize in quality improvement and accountability of post-acute care, such as the standards developed by the Commission on Accreditation of Rehabilitation Facilities (CARF) or other appropriate accreditors.

Financial Relationships between Hospitals and Post-Acute Care Providers

CPR welcomes the opportunity for hospitals to enter into financial relationships with “providers and suppliers” to share reconciliation payments, hospital internal cost savings, or both, and/or responsibility for repaying Medicare. CPR welcomes the fact that these “providers and suppliers,” or “CCJR Collaborators,” may include PAC providers including IRFs and outpatient therapy providers. CPR also welcomes the proposed rule’s statement that these collaborators should directly furnish related items or services to the beneficiaries, and/or participate in CCJR model lower extremity joint replacement (LEJR) redesign activities such as: attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries’ clinical courses; developing episode analytics; and preparing reports of episode performance.⁷

CPR is also supportive of the concept of the CCJR Sharing Arrangement, which participating hospitals and CCJR collaborators like PAC providers may elect to enter into, requiring their financial arrangement to be set out in writing and compliant with various limitations and requirements.

⁷ *Comprehensive Care for Joint Replacement Payment Model*, 41,262.

CPR also supports the possibility provided in the proposed rule that acute and post-acute providers and suppliers, in order to align their interests of the acute hospital, enter into gainsharing arrangements, so long as these arrangements comply with existing laws.⁸

Concerns of “Soft Steering” and “Hard Steering”

CPR supports the post-acute care beneficiary protections against improper referrals as proposed in the CCJR model. CCJR hospitals must provide beneficiaries with a complete list of all available PAC options in the service area.⁹ PAC providers listed must be consistent with medical need and include cost-sharing and quality information where applicable.¹⁰ Lastly, the CCJR model does not restrict the beneficiary’s freedom to choose providers, including surgeons, hospitals, PAC providers, or any other providers or suppliers.¹¹ CPR stresses that such patient choice provisions must be strictly enforced, regardless of the bundle-holders’ financial priorities.

That being said, “steering” of Medicare patients to certain providers may improve efficiency but this still often occurs at the expense of one of the paragons of Medicare policy: patient choice. “Soft steering” is a term often used to describe ways that hospitals and other providers can arrange systems of care that attempt to preserve patient choice to the maximum extent possible. CPR recommends that CMS exercise great caution if it permits “soft steering” by providers in bundled programs. CPR believes there can be negative consequences from this practice.

For example, in its April 2015 meeting, the Medicare Payment Advisory Commission (MedPAC) discussed the use of “soft steering” that would allow hospitals, under specified guidelines, to encourage the use of certain providers such as high quality, efficient providers. One concern is that the bundle-holder may not have an adequate understanding of the difference between providers or provider types (such as the difference between IRFs and SNFs). Additionally, the bundle-holder may drive patients to “low cost” providers in order to retain a greater share of the savings, but putting beneficiaries at clinical risk in the process and potentially stinting on care.

CPR believes that the CCJR model even goes as far as to promote “hard steering” that more harshly undermines the freedom of choice and care in the Medicare program. CPR opposes such hard steering. In fact, one stated goal of the CCJR model is to increase utilization of home health services and outpatient therapy, and reduced utilization of IRFs and SNFs post-joint replacement.¹² The CCJR model also encourages hospitals to recommend PAC settings that are “clinically appropriate” and “of the lowest acuity.”¹³ CPR also is concerned that the CCJR model will function like accountable care organization (ACO) networks, where while it will be mandatory to tell beneficiaries what providers are in network, it will not be mandatory to state out-of-network options. In this way, CPR believes that the model will deny patients knowledge of the availability of, and ultimately access to, IRFs where clinically appropriate.

⁸ The Proposed Rule does not establish any new exceptions to or waivers of applicable self-referral prohibitions, the anti-kickback statute, or the Civil Monetary Penalties (CMP) law. Instead, CMS expects all financial arrangements between acute care hospitals and CCJR collaborators, as well as any beneficiary incentives offered, to be structured in accordance with existing exceptions and safe harbors.

⁹ *Comprehensive Care for Joint Replacement Payment Model*, 41,250.

¹⁰ *Id.*, at 41,297.

¹¹ *Id.*, at 41,296, 41,313.

¹² *Id.* at 41,254.

¹³ *Id.* at 41,268.

Alternatively, bundle-holders could “steer” patients to providers with which they have financial relationships with regardless of clinical need. In any event, bundle-holders should be required to continue to inform beneficiaries of their freedom of choice rights.

Therefore, CMS should carefully consider how CCJR providers can be given the flexibility to develop innovative relationships and require beneficiary protections, such as quality metrics, that ensure patients receive clinically appropriate care.

All Prosthetics, Orthotics and Custom DME Should Be Exempt from the Bundle

CPR recommends the exclusion from the CCJR bundle of all prosthetic limbs and orthopedic braces. CPR would also support a further exclusion of customized durable medical equipment (currently included in the bundle),¹⁴ particularly mobility devices known as “complex rehabilitative technology” (CRT)¹⁵ and their related accessories as well as Speech Generating Devices (SGDs). CPR believes that certain devices and related services should be exempt from the bundled payment system as they are critical to an individual in returning to full function and would likely be delayed or denied under a bundled payment system. All customized devices (such as prosthetics, orthotics, CRT and SGDs) that are relatively expensive and intended to be used by only one person should be separately billable to Medicare Part B during the 90-day bundled period. These devices and related services are critical to the health and full function of people with limb loss and other disabling conditions. Not all Medicare beneficiaries require prosthetics, orthotics, CRT and/or SGDs, but these devices are critical to the health and function of some patients. Under a bundled payment system, there are strong financial incentives to delay or deny entirely access to these devices and related services until the bundle period lapses. Once this occurs, Medicare Part B would be available to cover the cost of these devices, but this delay is very deleterious to patient outcomes, and opportunities are lost for rehabilitation and training on the use of the device or technology during their stay.

This phenomenon was witnessed when Congress implemented prospective payment for skilled nursing facilities (“SNFs”) in 1997 and initially included orthotics and prosthetics in the SNF bundle or prospective payment system (“PPS”).¹⁶ As a result, most SNFs began to delay and deny access to prosthetic and orthotic care until the beneficiary was discharged from the SNF and then Medicare Part B assumed the cost of O&P treatment. During this period, Medicare patients experienced inappropriate and unreasonable delays in access to orthotic and prosthetic care that often make the difference between independent function and life in a nursing home. In 1999, Congress recognized this problem and exempted a large number of prosthetic limb codes from the SNF PPS consolidated billing requirement,¹⁷ thereby permitting these charges to be passed through to Medicare Part B during the SNF stay.¹⁸ As a result, SNF patients once again had access to prosthetic care during the course of their SNF stay. This experience should not be repeated under new bundled payment systems and, therefore, we recommend that CMS exempt all prosthetics, custom orthotics, CRT and SGDs from any bundling regulation.

¹⁴ *Id.* at 41,308.

¹⁵ Bipartisan legislation has been introduced in both houses of Congress to create a separate designation under the Medicare program for CRT entitled, “Ensuring Access to Quality Complex Rehabilitation Technology Act of 2014,” H.R. 1516 and S. 1013.

¹⁶ Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4432, 111 Stat. 251, 414 –22 (1997) (codified at 42 U.S.C § 1395yy).

¹⁷ Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, § 103, 113 Stat. 1501A-321, 1501A-325–26 (1999) (codified at 42 U.S.C § 1395yy(e)).

¹⁸ Unfortunately, Congress did not similarly exempt custom orthotics from the SNF consolidated billing requirements which has led to a serious lack of access to appropriate custom orthotic care in the SNF setting.

Exemption of Certain Vulnerable Patients from Bundling

Bundling that includes PAC services is a concept that is clearly untested at this time, and we strongly favor fully developed quality measures and risk-adjusted payment systems so that savings are not achieved by stinting on patient care to protect vulnerable Medicare beneficiaries. Among these are Medicare patients with brain injuries, spinal cord injuries, moderate to severe strokes, multiple-limb trauma, amputations, and severe neuromuscular and musculoskeletal conditions. While this is clearly a minority of Medicare beneficiaries, it is a very important subgroup that, we believe, should be exempt from any bundled payment system. As stated above, CPR supports CMS' proposal that those with acute disease diagnoses, namely those with severe head injury, will be excluded from the bundle.¹⁹ We believe the most vulnerable patients should only be included in bundling on a mandatory basis when the bundled payment systems can demonstrate sufficient positive quality outcomes, risk adjusters, and patient safeguards to ensure quality care. CPR opposes the current inclusion of those with chronic kidney disease for those reasons.²⁰

Appropriate PAC Quality and Outcome Measures

CPR recommends that quality measures be particularly strong in the CCJR model, especially with regard to patient experience and pain measures. Patient experience measures should be administered frequently to counterbalance the economic interests of the hospitals. Pain measures should be conducted every day, and long-term measures should be conducted in intervals of three months, six months, nine months, and one year following the procedure to guarantee the best care.

Quality measures must be mandated in any bundling regulation to assess whether patients have proper access to necessary care. This is one of the most important methods of determining whether savings are being achieved through better coordination and efficiency, or through denials and delays in services. Uniform quality and outcome measures that cross the various PAC settings do not currently exist. The existing LTACH CARE instrument for LTACHs, the IRF-PAI for rehabilitation hospitals, the MDS 3.0 for SNFs, and the OASIS instrument for home health agencies, are all appropriate measurement tools for each of these settings. But they measure different factors, are not compatible across settings, and do not take into consideration to a sufficient extent a whole series of factors that truly assess the relative success of a post-acute care episode of care. For instance, before widespread bundling that incorporates PAC services is adopted, measures must be incorporated into the PAC system as follows:

- **Function**: Incorporate and require the use of measures and measurement tools focused on functional outcomes, and include measurement of maintenance and the prevention of deterioration of function, not just improvement of function;
- **Quality of Life**: Require the use of quality of life outcomes (measures that assess a return to life roles and activities, return to work if appropriate, reintegration in community living, level of independence, social interaction, etc.);²¹
- **Individual Performance**: Measurement tools should be linked to quality outcomes that maximize individual performance, not recovery/rehabilitation geared toward the “average” patient;

¹⁹ *Comprehensive Care for Joint Replacement Payment Model*, 41,215, 41,308.

²⁰ *Id.*, at 41,215.

²¹ These extended functional assessment and quality of life measures are consistent with the World Health Organization's International Classification of Function, Disability and Health (ICF) and the measurement tool designed around the WHO-ICF known as the AM-PAC.

- **Access and Choice:** Measures should include assessment of whether the patient has appropriate access to the right setting of care at the right time and whether the patient is able to exercise meaningful choice; and
- **Patient Satisfaction:** Measures should not be confined to provider-administered measures but should directly assess patient satisfaction and self-assessment of outcomes. CMS or MedPAC should be required to contract with an independent entity to conduct studies in this area and factor the results into any final bundled payment system incorporating PAC services in the future.²²

Create Financial Disincentives Preventing Clinically Inappropriate Diversion of Patients to Less Intensive Settings

CPR believes that, while CMS intends to evaluate the CCJR model, on, among other things, “unintended consequences” including “evidence of stinting on appropriate care” and “evidence of inappropriate referrals practices,”²³ inappropriate stinting of care remains a major concern of the CCJR model. As mentioned above, one stated goal of the CCJR model is to increase utilization of home health services and outpatient therapy, and reduce utilization of IRFs and SNFs post-joint replacement.²⁴ The CCJR model also encourages hospitals to recommend PAC settings that are “clinically appropriate” and “of the lowest acuity.”²⁵

CPR also does not support CMS’ proposal to use Medicare Spending per Beneficiary (MSPB) as a benchmark for the CCJR model. According to the proposed rule:

In order to operationalize the exclusion of the various special payment provisions in calculating episode expenditures, we propose to apply the CMS Price (Payment) Standardization Detailed Methodology described on the QualityNet Web site at <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350>. This pricing standardization approach is the same as used for the HVBP program’s Medicare spending per beneficiary metric.²⁶

CPR believes that using MSPB as a benchmark will create a significant financial incentive to not treat patients at IRFs, even when clinically necessary, as care is more expensive in these settings in the short-term, and care in IRFs will reflect poorly on hospitals’ MSPB scores. Further, MSPB scores do not reflect long-term savings or functional improvements.

Therefore, in order to protect against diversion of patients to less intensive, inappropriate PAC settings, we recommend that any bundling regulation include instructions to the HHS Secretary that payment penalties should be established to dissuade bundle-holders from underserving patients.

²² “uSPEQ”® (pronounced “You Speak”) is an example of a patient satisfaction assessment tool developed by CARF, International, that measures end users’ experience with post-acute care. The survey can be answered by the patient, family or caregiver.

²³ *Comprehensive Care for Joint Replacement Payment Model*, 41299.

²⁴ *Id.* at 41,254.

²⁵ *Id.* at 41,268.

²⁶ *Id.* at 41,222.

Reduction in Scope

Due to the concerns expressed above, CPR advocates that instead of a mandatory bundling model incorporating 75 Metropolitan Statistical Areas (MSAs), CMS should implement the CCJR model in a voluntary bundling model incorporating no more than 5-10 MSAs.

We greatly appreciate your attention to our concerns and your interest in our participation in this process. Should you have further questions regarding this information, please contact Steven Postal, CPR staff, by emailing Steven.Postal@ppsv.com, or by calling 202-466-6550.

Sincerely,

CPR Steering Committee

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