



VIA ELECTRONIC MAIL

June 1, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human
Services
200 Independence Ave., SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 20201

Adam Boehler
Director
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 20201

RE: Need for Functional Outcome Quality Measures to Prevent Stinting on Patient Care in the Bundled Payments for Care Improvement (BPCI)—Advanced Initiative

Dear Secretary Azar, Administrator Verma, and Director Boehler:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR), the Consortium for Citizens with Disabilities (CCD) Health Task Force, the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition and other supporting organizations write to comment on the new voluntary bundled payment model, Bundled Payments for Care Improvement—Advanced (BPCI-Advanced) initiative. Bundled payment systems seek to reduce expenditures and improve quality of care for Medicare beneficiaries in the fee-for-service program. However, without requirements to measure functional outcomes, patient/beneficiary experience, and beneficiary satisfaction, we have serious concerns that bundled payment systems may stint on patient care, particularly rehabilitation services and devices.

We submit these comments despite the fact that the Center for Medicare and Medicaid Innovation (CMMI) did not provide an opportunity for public comment on its BPCI-Advanced announcement on January 9, 2018. We ask CMMI to consider our comments as CMS staff assess the bundling proposals submitted in the first round of BPCI-Advanced, which is scheduled to be implemented on October 1, 2018, as well as in the second application period starting January 1, 2019.

It is important to note that while this comment letter relates specifically to the BPCI-Advanced announcement, the concepts in this letter equally apply to any Alternative Payment Model (APM) that significantly impacts rehabilitation post-injury or illness, including Accountable Care Organizations (ACOs), shared savings models, and even Medicare Advantage plans.

First, we would like to thank you for issuing final regulations in the fall of 2017 that withdrew the mandatory Cardiac Rehabilitation Incentive Payment Model and limited the scope of the Comprehensive Care for Joint Replacement (CJR) mandatory bundling model. We believe that *mandatory* bundling models, among other things, compromise beneficiary choice of provider, a powerful quality assurance mechanism. Beneficiaries who choose to remain in the Medicare fee-for-service program do so, in part, to maximize patient choice of provider despite ample opportunities to join the Medicare Advantage program where they may obtain additional benefits and cost-sharing but must agree to be served by a more limited provider network.

To CMMI's credit, BPCI-Advanced is a *voluntary* payment model that bundles a specific episode of care (e.g., 90-days) into one lump-sum payment that CMS provides to an Acute Care Hospital (ACH) or a Physician Group Practice (PGP) and allows the bundle-holder flexibility to treat the patient as they deem appropriate. The bundle holder must record data on certain quality metrics and is paid financial incentives if a defined spending target is met while maintaining or improving performance.

BPCI-Advanced applies to thirty-two (32) clinical episodes. Depending on the severity of the condition, many of these episodes require significant inpatient and/or outpatient rehabilitation services and devices, including intensive, coordinated and interdisciplinary medical rehabilitation services, to regain or improve functionality after illness or injury. These episodes include, but are not limited to:

- Stroke
- Back and neck surgery except spinal fusion
- Spinal fusion
- Cervical spinal fusion
- Combined anterior posterior spinal fusion
- Acute myocardial infarction
- Cardiac arrhythmia, defibrillator, or valve
- Chronic obstructive pulmonary disease
- Congestive heart failure
- Coronary artery bypass graft
- Major joint replacement of the lower or upper extremity

- Hip and femur procedures except major joint; and,
- Double joint replacement of the lower extremity.

CMMI chose seven quality measures for the BPCI-Advanced model. None of these required quality measures include an assessment of the patient's functional status either before or after post-acute care (PAC). In short, while CMMI *encourages* bundled payment applicants to monitor functional outcomes, it does not *require* participants to measure functional status. Given the results of the third annual evaluation of the BPCI program discussed below and the serious deficiencies this CMS report exposed in providing for Medicare beneficiary's post-acute care needs under these models, ***it is alarming that CMMI has chosen to move forward with a new round of bundling proposals that do not mandate reporting and payment consequences for failure to achieve quality outcomes related to patient functional status or patient experience/satisfaction.***

It is relatively easy to reduce Medicare Spending Per Beneficiary (MSPB) under bundled payment systems by denying patient access to timely and intensive rehabilitation services and diverting beneficiaries with the above-cited conditions to less intense levels of post-acute care. It is also relatively easy to reduce post-acute care costs by limiting or restricting the amount, duration, and scope of rehabilitation services and devices.

Our organizations believe functional measures are necessary to assure bundling as a payment model does not jeopardize access to medically necessary rehabilitation services and devices. Absent the inclusion of functional measures in this and other demonstrations or delivery models, our groups could find it difficult, if not impossible, to embrace payment models that utilize bundling altogether. The lack of requirements to measure functional outcomes is a major shortcoming of the BPCI-Advanced model and we, therefore, have serious concerns with it as written.

We strongly urge CMMI to score most favorably applications that incorporate robust functional outcome measures, and work with applicants to ensure that strong functional measures are added to CMMI-approved BPCI-Advanced bundling programs. We encourage CMMI to consider measures that assess functional outcomes at time intervals that are longer than the 90-day bundling period (e.g., at 6-months or one year post-discharge). Functional outcome measures must be directly linked to financial incentives if they are to be effective in preventing stinting of patient care, particularly rehabilitation services and devices.

The remainder of this letter focuses on the BPCI-Advanced model's designated quality measures, the lessons that should have been learned from the third annual BPCI evaluation performed by CMS, and recommendations for improvement that we hope CMMI will adopt as it assesses and approves applications under the BPCI-Advanced model in both the first and second cohorts of applications.

I. Functional Outcome Measures

The undersigned organizations have serious concerns that the designated quality measures for the BPCI-Advanced model will not adequately assess whether participating providers and

practitioners render the most appropriate care necessary for patients to regain their maximum level of health, function, and independent living. Under BPCI-Advanced, CMMI will examine seven mandatory quality measures:

1. All-cause Hospital Readmission Measure (NQF #1789);
2. Advanced Care Plan (NQF #0326);
3. Perioperative Care: Selection of Prophylactic Antibiotic: First or Second Generation Cephalosporin (NQF #0268);
4. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550);
5. Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft Surgery (NQF #2558);
6. Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (NQF #2881); and,
7. AHRQ Patient Safety Indicators (PSI 90).

Two of these quality measures—All-cause Hospital Readmission Measure and Advanced Care Plan—are required for every clinical episode. The remaining five quality measures will apply to certain clinical episodes. Measuring the number of hospital readmissions is an important quality metric but without strong functional measures, providers are only incentivized to provide just enough care to avoid a readmission to the acute care hospital. This is a seriously low bar for quality in bundled payment models which must be corrected.

The mandatory quality measures only provide a partial glimpse of the impact of BPCI-Advanced on the quality of care provided to Medicare fee-for-service beneficiaries. The seven quality measures fail completely to gauge the functional status, overall patient experience, or satisfaction of the beneficiary receiving care under the BPCI-Advanced model. We have serious concerns that Medicare beneficiaries may be seriously underserved if sufficient functional outcome and patient satisfaction measures are not included in these bundled payment programs. We are similarly concerned that such quality measures must be granular enough to truly assess whether bundled payment participants achieve savings through streamlined processes and efficiencies in care, or reduce program spending simply by being diverted away from post-acute care settings that are more intensive, and perhaps expensive, in the short term.

There are significant unnecessary long term costs to the system created by the diversion of patients to less intensive post-acute care settings and restrictions in the amount, duration, and scope of rehabilitation services and devices. Readmission to the acute care hospital is clearly one of these potential costs, however, disability and lack of function create far greater expenditures in the long term than the savings achieved through bundling payment in the short-run. Less independent living, more sedentary lifestyles, greater dependence on home care, and greater reliance on mobility aids and equipment contribute to high, long-term costs that could be averted through timely, intensive and appropriate rehabilitation services and devices. Of course, the human cost and impact of denied medically necessary care can be tragic.

II. CMS Should Adhere to the Lessons in its Own Evaluation of BPCI

The BPCI-Advanced Fact Sheet on CMS' website states that "BPCI Advanced builds upon lessons gleaned from current and previous CMS models, demonstrations, and programs," but the complete lack of functional outcome measures in the BPCI-Advanced model suggests otherwise. This is particularly troubling given the adverse health effects observed in the third annual evaluation and monitoring report on Models 2, 3, and 4 of the BPCI initiative.¹

CMS' own report revealed a pattern in Model 2—the same model that forms the basis of BPCI-Advanced—that "BPCI participants attempted to reduce episode payments by reducing institutional PAC use and increasing use of [home health agencies (HHAs)], a strategy numerous BPCI participants have indicated they employ."² The percentage of beneficiaries discharged to institutional PAC settings declined in approximately two-thirds (61%) of clinical episodes in Model 2 where the acute care hospital holds the bundled payment.³ This decline was statistically significant for three clinical episodes: major joint replacement of the lower extremity (MJRLE), cardiac valve, and other respiratory.⁴

Model 2 hospital episode initiators (EIs) "reduced the share of their MJRLE patients who were discharged to institutional PAC from 62.5% to 52.3% while the comparison group reduced the share discharged to institutional PAC from 61.2% to 56.9%."⁵ Relative to the comparison group, inpatient rehabilitation facility (IRF) payments declined by \$435, and skilled nursing facility (SNF) payments declined by \$711 under Model 2.⁶ Meanwhile, in nineteen of the twenty-three Model 2 clinical episodes, HHA payments increased.⁷

CMMI has pointed to this reduction in institutional post-acute care use as an effective way to reduce Medicare expenditures. But without strong functional measures to assess whether beneficiaries are receiving the post-acute care they need, these cost reductions could be extremely penny-wise and pound-foolish. We have serious concerns that providers and practitioners under the BPCI program could be stinting on post-acute care to achieve savings.

In fact, additional sections of the third annual evaluation and monitoring report on the BPCI initiative suggest our concerns are well-founded. BPCI participants in Model 2 "reduced institutional PAC [length of stay] as a strategy to reduce Medicare fee-for-service payments," and this, in turn, "may have resulted in a sicker PAC patient population with less time to recover."⁸ An analysis of Model 2 of the BPCI initiative found that for fourteen activities of daily living (ADL) measures, there was a statistically significant relative decline in the

¹ The Lewin Group, *CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 3 Evaluation & Monitoring Annual Report* (Oct. 2017), <https://downloads.cms.gov/files/cmmi/bpci-models2-4yr3evalrpt.pdf>.

² *Id.* at ES-6, 82.

³ *Id.* at ES-5.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.* at 92.

proportion of BPCI patients discharged to an SNF, IRF, or HHA who improved over the course of their stay.⁹

These results do not paint a picture of success for CMS's BPCI initiative from a rehabilitation/patient care standpoint. CMS was able to evaluate the impact of the BPCI initiative on the quality of care, utilization of health care services, and payment by measuring numerous outcomes, including functional status outcomes and patient experiences. These measures are conspicuously absent from the BPCI-Advanced model and they are the very measures that would enable CMMI to determine whether savings are being achieved through better coordination and efficiency, or through denials and restrictions in rehabilitation services and devices. Without adequate functional measures in bundled payment programs, beneficiaries risk being coerced, not being appropriately informed of their post-acute care options, and being denied services to which they are entitled under the Medicare program.

III. Recommendations for CMMI's Assessment of BPCI-Advanced Applications

In light of our organizations' concerns and CMS's own evaluation of the BPCI program, we strongly urge CMMI to score BPCI-Advanced applications that incorporate robust functional outcome and patient satisfaction measures most favorably, and work with all applicants to ensure that strong functional outcome and patient satisfaction measures are added to CMMI-approved BPCI-Advanced programs. As already stated, these measures must be directly linked to financial incentives if they are to be effective in preventing stinting of patient care, particularly rehabilitation services and devices.

The specific functional status measures, as well as any patient experience or satisfaction metrics, employed by CMMI under the BPCI-Advanced model should be endorsed by the National Quality Forum (NQF) to assure validity and reliability. These measures should focus on factors that include improvements in ADL function but extend well beyond these rudimentary measures. CMMI should also include measures related to discharge rates to the community, improvement in quality of life, pain management, reintegration to community living, level of independence, degree of social interaction, as well as patient experience and patient satisfaction with the care provided.

IV. Permitting PAC Providers to Hold the Bundled Payment

The undersigned organizations regret the fact that CMMI has limited BPCI-Advanced to only one model that provides all of the financial incentives to the Acute Care Hospital or Physician Group Practice. Under Model 3 of the BPCI program, post-acute care providers were able to hold the bundle with an assumption that these providers were not only more invested in PAC services, but knew the potential for improvements in patient care when the beneficiary is timely and appropriately referred to the proper setting and level of intensity of post-acute care.

Under BPCI-Advanced, PAC providers will no longer be able to hold the bundled payment, which puts an end to pilot programs and demonstrations that may have been instructive in designing bundled payment programs that do not stint on post-acute care. We are concerned that

⁹ *Id.*

the ACH and PGP bundle-holders may inappropriately drive patients to “lower cost,” lower intensity PAC providers and generally limit access to rehabilitation services and devices in order to retain a greater share of the financial incentive. Without robust functional outcome and patient satisfaction measures, we fear this result may be inevitable.

CPR is a coalition of national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care in a variety of inpatient and outpatient settings so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function.

CCD is a national coalition of over 100 organizations that advocate on behalf of people with mental, physical, developmental, and intellectual disabilities in a wide variety of subject matter areas, including health care and long term services and supports.

ITEM Coalition is a 75-member coalition of national consumer and provider organizations that promotes access to and coverage of assistive devices and technologies for people with disabilities and chronic conditions of all ages.

We greatly appreciate your attention to our concerns. For additional information or if you have questions, please contact Peter Thomas by emailing Peter.Thomas@Powerslaw.com or by calling 202-466-6550.

Sincerely,

Supporting Organizations within CPR, CCD and ITEM Coalitions

Academy of Spinal Cord Injury Professionals (ASCIP)
ACCSES
American Academy of Physical Medicine and Rehabilitation (AAPM&R)
American Association of People with Disabilities
American Association on Health and Disability
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine (ACRM)
American Dance Therapy Association
American Foundation for the Blind (AFB)
American Music Therapy Association
American Physical Therapy Association (APTA)
American Spinal Injury Association (ASIA)
American Therapeutic Recreation Association
Amputee Coalition
The Arc of the United States
Association for Education and Rehabilitation of the Blind and Visually Impaired (AER)
Association of Academic Psychiatrists
Association of Assistive Technology Act Programs

Association of Rehabilitation Nurses
Association of University Centers on Disabilities (AUCD)
Autistic Self Advocacy Network
Brain Injury Association of America
Caregiver Action Network
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Clinician Task Force
Disability Rights Education and Defense Fund (DREDF)
Falling Forward Foundation
Lakeshore Foundation
The Myositis Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Councils on Developmental Disabilities
National Association of State Head Injury Administrators
National Disability Rights Network
National Rehabilitation Association
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
The Simon Foundation for Continence
Unite 2 Fight Paralysis
United Spinal Association

Additional Supporting Organizations

American Academy of Neurology (AAN)
American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM)
Spine Intervention Society