THE NETWORK FOR EXCELLENCE IN HEALTH INNOVATION

A Bundle of Potential and Risk: Bundled Payment and its Impact on Innovation

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INTRODUCTION

Health care payment reform is moving quickly in the United States, with more than two-thirds of reimbursements expected to be tied to some form of value-based payment by 2020.[1] Bundled payments have emerged as a promising tool in this new wave of risk-shifting, and stakeholders across the country – including Medicare, Medicaid, employer groups, and commercial health plans – are recognizing the model's potential in addressing some of the issues of over-utilization of services and fragmented care. Bundles, generally defined as a predetermined payment for an episode, or group of related health services, require providers to assume some financial accountability and adhere to established quality metrics.

As this model continues to evolve, many have observed its implementation with little attention paid to its impact on medical advancement and innovation. There remain serious concerns that require further consideration, including bundles' quality standards and influence on clinical experimentation. NEHI (Network for Excellence in Health Innovation) has been at the forefront of this discussion, and convened in July 2014 two expert roundtables of stakeholders from across the country – including Center for Medicare and Medicaid Innovation (CMMI), provider, employer, payer, patient group, and industry leaders (see Appendix). This Issue Brief reflects findings from the event, in addition to background research and expert interviews conducted by NEHI on what this changing landscape means for patient access to innovative therapies and medical devices.

AN EXPANDING LIST OF DISEASE AREAS

Bundled payments began in the 1980s through small pilot programs and have gained traction since then for many reasons, including the Affordable Care Act's (ACA) encouragement of gain-sharing programs, pervasive use and availability of data, and the country's largest payer, Medicare, becoming involved.[2] Additionally, it has become easier for systems to leverage already proven models over time.

Early bundled payment demonstrations established a proof-of-concept for the model but were limited in scope. Most of these programs were narrowly defined to surgical procedures, such as short-term cardiac and orthopedic procedures in the inpatient setting, which have discernable start and end points along with clear definitions of success. In many ways this is still the

norm: as of 2013, 87 percent of bundles were for surgical conditions, 91 percent of which were within the cardiac or orthopedic space.[3]

However, policymakers now are trying to bring the model to scale in other costly areas – such as chronic disease, behavioral health, and oncology – but these medical areas are also more complex and thus the challenges and concerns for bundled payments are greater.

Bundled payments have been generally absent from chronic disease and behavioral health over the years due to logistical challenges, including limited past examples available to help guide implementation, no solid consensus on treatment regimen, or agreement of what complications should be included as a disease-related cost.[4] Nevertheless, some key players are looking to break ground. CMMI has issued a Request for Information (RFI) on bundling complex, chronic disease in the outpatient setting, and state programs, like Arkansas' Medicaid, are beginning to see tremendous opportunity in behavioral health bundles given the prevalence of mental illness in Medicaid populations.[5] (See Figure 2)

While oncology bundles face similar challenges, more progress has been made in this area, with multiple initiatives emerging in the private market and CMMI's ongoing development of a new multi-payer oncology bundling initiative.

A serious debate is emerging over what types of procedures are appropriate for bundling. The answer is likely to be realized over the next few years as more players become involved and others pioneer new efforts.

AN EXPANDING LIST OF PLAYERS

As the list of bundled disease areas continues to grow, so does the list of participants implementing these programs. The common thread between all of these programs is the desire to reduce practice variation and control spending in high cost disease areas. However, due to widespread experimentation with the model, bundles vary significantly in terms of level of risk; type of payment (retrospective or prospective); the incorporation, or not, of post-acute services; length of the episode; disease areas; and setting: national, state, commercial, or employer-led.

National Models

Bundled payments have taken the country by storm, and the Centers for Medicare and Medicaid Services (CMS) has been leading the charge, testing various pilots in different episodes and types of settings. Bundling has for a long time been considered a possible remedy for the serious variation in Medicare expenditures across the country,[6,7] and the Affordable Care Act recently reawakened interest in the model by calling for a more expansive Medicare bundling program, now known as the Bundled Payment for Care Improvement (BPCI). (See Figure 1)

Figure 1: Bundled Payment for Care Improvement (BPCI)

Building off past successful bundled payment demonstrations – like the Acute Care Episode[8] and Participating Health Bypass Center[9] programs – the Center for Medicare and Medicaid Innovation (CMMI) began testing four models in 2013 in both acute and post-acute settings. This new demonstration program, Bundled Payment for Care Improvement (BPCI), has so far had notable achievement within 48 episodes (per the table below) and has caught significant interest among provider groups. In August 2014, CMS announced that thousands more participants would be joining the program, making it the largest voluntary program within Medicare of more than 6,000 participants.[10]

BPCI Participant	Model	Type of facility	Episode	Average Savings/Case	Annualized 2014 Savings
A	Model 3; Retrospective	Full service post-acute care	Orthopedic	$2,300	$3,000,0000
B	Model 4; Prospective	Non-profit health system	Orthopedic and cardiovascular	$1,300	$1,232,400
C	Model 4; Prospective	Multi-facility integrated delivery system	Cardiovascular	$2,667	$544,068
D	Model 2; Retrospective	Community hospital, focus in general and orthopedic surgery	Orthopedic	$1,164	$75,671

Source: data courtesy of The Camden Group

CMMI has shown notable success with BPCI and has also signaled interest in expanding its impact through new specialty episode models in the outpatient setting. CMMI is interested in opportunities not only in the procedural space, but also within complex and chronic disease management. [11]

Additionally, CMMI is in process of designing an oncology bundled payment strategy, an Oncology Care Model (OCM), that would include most cancer types, apart from rare cancers that might be difficult to price-set, and all Medicare expenditures (A, B, and D). Among the program's many requirements, participants would be required to treat patients in compliance with nationally-recognized clinical guidelines and adhere to 32 quality metrics, eight of which will be used to determine performance-based payment. CMMI is hoping to have OCM be a multi-payer model that could align incentives among commercial and pubic payers and make the transition easier for practices interested in becoming involved.[12,13]

State Models

Several states are also in the process of leading bundled payment programs with support from CMMI, recognizing the opportunity to drive standardization and consistent practice patterns in areas where there is significant high cost and variability for their populations. Arkansas' Health Care Payment Improvement Initiative is ahead of the curve in many ways, and is the first mandatory, multi-payer demonstration model of bundled payment in the country.

Figure 2: Arkansas Health Care Payment Improvement Initiative

Since 2012, Arkansas' multi-payer initiative has been testing bundled payments in more than a dozen episodes, including several less traditional episodes like ADHD, Asthma, and oppositional defiance disorder, in which all pharmacy costs are included. Arkansas Medicaid has noted significant improvements gathered from the first year of episode claims and quality data, including a dramatic decrease in ADHD therapy visits and cost stabilization within episodes for hip and knee replacements and congestive heart failure.[14]

"The first round of performance reports from our multi-payer payment transformation efforts is very promising. Quality metrics show improvement and the financial impact — gain sharing and claw-backs — influenced providers. But most importantly, providers sense a new opportunity to reassert clinical leadership and guide needed change."

- *Joseph W. Thompson, MD, MPH, Surgeon General for the State of Arkansas and Director, Arkansas Center for Health Improvement*

Employer Models

Self-insured employers have for a long time realized the promise of bundled payments, and several have been involved in longstanding arrangements with high performing health systems across the country. These systems are able to provide consistent, high-quality care at a discounted price for employees. For example, Lowe's has contracted with a leading cardiology hospital, Cleveland Clinic, over the last 17 years for heart surgery procedures. Lowe's has saved significant upfront costs for nearly every operation, despite covering travel expenses for its employees and without accounting for downstream savings, such as readmissions and employee productivity. Lowe's is expecting to see similar benefits through its involvement with a new multi-employer bundling initiative, The Employers Centers of Excellence, arranged by the Pacific Business Group on Health.[15] (See Figure 3)

Figure 3: Pacific Business Group on Health's Employers Centers of Excellence

In January 2014, several leading employers joined the Pacific Business Group on Health's Centers of Excellence Network (ECEN). ECEN coordinates bundled payment agreements with four hospital systems that offer knee and hip replacements under a discounted, bundled rate for employees willing to travel at no personal cost.

Enthusiasm is growing for this program and current participants include:

Walmart	***Johns Hopkins***
Lowe's	***Kaiser Permanente Orange County***
McKesson	***Mercy Hospital***
	Virginia Mason

As of July 2014, ECEN had more than 1,500 unique inquiries and more than 300 completed surgeries, along with 100 surgeries scheduled and 80 more under review. ECEN is now in the process of expanding into other procedural areas and is looking to have several Centers of Excellence open for spinal surgeries by January 2015.[16]

Commercial Models

There is also tremendous movement taking hold in the private market across the country.[17] Many commercial plans have for years been involved with bundling and are more recently expanding their programs into complex disease areas. Horizon Blue Cross Blue Shield is one payer that has been increasingly pursuing new applications for bundled payments for pregnancies, deliveries, and joint replacements, and now is involved in breast cancer episodes as well.

Horizon's program is among many commercial efforts to curb costs within oncology treatment, which is expected to reach up to $173 billion in annual national expenditures by 2020.[18] United Healthcare has been piloting bundled payments in oncology but has employed a very different strategy than Horizon to confront the issue of surging cancer costs. (See Figure 4) United's goal is to remove any adverse incentives tied to prescribing chemotherapy drugs by carving out costs for these therapies, while Horizon focuses on normalizing practice patterns through clinical pathways.

Figure 4: UnitedHealthcare Oncology Bundled Payment Pilot

UnitedHealthcare recognized the opportunity for oncology bundles recently, with cancer costs accounting for 11 percent of its budget and rising steadily. A pilot bundling program was instituted from 2009 to 2012 among five participating sites, covering more than 810 patients within 19 various clinical conditions of breast, colon, and lung cancer diseases. Through some episodic payment and carve outs for the cost of therapies, United demonstrated a 34 percent decrease in total medical costs without a sacrifice in quality of care. These tremendous savings were in spite of a 179 percent increase in chemotherapy drug costs.[19]

Physicians were given freedom to change their preferred drug as they wished as new data became available, which happened several times throughout the course of the pilot. Participants were able to find solutions and efficiencies that worked best within their systems, including reducing utilization rates of imaging services, optimizing discharge processes, and scheduling check-ins sooner.[20]

IMPLICATIONS FOR INNOVATION

Across the country, the benefits of bundled payments are being demonstrated within clearly defined procedures, and are showing promise in other high cost, less defined medical areas. As these programs continue to expand and test new frontiers, the impact on patient access to innovative therapies and technologies is largely unknown. Now is the time to consider the potential challenges and risks to innovation in this evolving payment environment, and put forth a strong multi-sector effort to confront them.

Quality of Care

While the traditional fee-for-service system brings with it well deserved concerns about overutilization, in this new era of risk shifting, the health care system may be facing the contrary effect: an underutilization of appropriate services. It is critical that adequate quality metrics be built into models to safeguard against potential underuse of services, particularly in regard to the adoption of valuable, but costly therapies within episodes of care.

Experts agree that quality metrics within these models are not robust enough to account for an appropriate range of outcomes, particularly in complex disease states in which bundles are growing.

Quality metrics are often more concerned with quantifiable outcomes, overlooking more progressive, but just as important, measures like long-term outcomes and patient reported outcomes such as patient satisfaction and quality of life.

Further, due to the short-term focus of bundles, metrics may overlook potential benefits that therapies provide outside of the relatively short window of a bundled payment, which is often structured over 30, 60, or 90 days. For new innovations that have been developed to meet marks outside of these time frames, there is no guarantee that these outcomes will be recognized or rewarded through reimbursement.

Experimentation and Adoption of New Innovations

Along the same lines, strict adherence to clinical guidelines and assigned therapies could jeopardize clinical experimentation and the adoption of new innovations without appropriate pathways for experimentation. The demonstration and adoption of new innovations in the real-world is dependent on experimentation by early adopters in the health care system. Bundles' sharp focus on cost and short time windows may discourage providers from tailoring treatments to individual patient's needs and thus could harm the innovation ecosystem and personalized care.

If new data show that a certain therapy leads to significant outcomes, it is often unclear how the bundle will account for that new innovation, especially if that drug is more expensive than what is originally accounted for in the bundle. Bundling products and strict adherence to clinical pathways could slow innovative approaches to treatment, especially for medical areas like cancer that rely on innovative and often experimental care.

The Innovation Ecosystem

All this creates an uncertain environment for innovators. Without clear signs from the health care system on quality targets in which to aim and that proven innovations will be reimbursed, incentive for innovators to invest in the development of future innovations may be harmed.

Bundling may also impact medical research within academic medical centers (AMCs), which have been a vital leader in testing and establishing the value of innovations over the years. If AMCs now have to compete on cost, their ability to cross-subsidize research, train the next generation of physicians, and provide novel care may be impeded. Further complicating the issue is the reality that National Institutes of Health (NIH) funding has drastically decreased in recent years.[21,22]

As bundled payments and other value-based payment reforms continue to grow, it becomes important to address where leading health systems, like AMCs, will get the money to continue this innovative work, and how innovators can be incentivized to create products that align with the shift toward value in the U.S health care system.

CONCLUSION

Given that bundled payments likely are here to stay as the number of players and programs continue to expand, the following topics require further consideration:

Creating Adequate Safeguards for Innovation

There must be some mechanism within bundled payment arrangements to encourage adoption of new and proven technologies into routine practice.

> ***"Moving forward, we need to make sure that whatever policy we create is not freezing, in that piece of time, the option for innovation for the patients."***
>
> - ***Ryan Hohman, Friends of Cancer Research***

Possible options include carve-outs as evidenced through the UnitedHealthcare example, add-on payments, or other clearly defined mechanisms for clinicians to tailor treatments to patients' individual needs when predefined clinical guidelines are insufficient. Episodes that rely heavily on guidelines must be able to accommodate new innovations that match patient preference and experience. Clinical flexibility must be addressed from the outset of bundled payment construction, to ensure physician autonomy and to promote the idea that not every patient will fit a guideline.

Bundled payments do not need to be strictly prescriptive to be successful, as physicians are enormously innovative and can transform care processes while curbing costs if incentivized properly.

Collaborating to Demonstrate Value

Additionally, there is tremendous opportunity for industry to partner with payers and providers to better understand the impact of their products and needs of the health care system in this new environment. Manufacturers should continue to collect and promote evidence on cost and clinical effectiveness to support adoption of their innovations, and also work with other stakeholders to collect information on how therapies might demonstrate value in the long term. These data partnerships can allow manufacturers to gain feedback and data on their products in real time and earlier in the product development process, thus helping create more impactful therapies and improve upon already established technologies.

> ***"We can be helpful to our customers in doing some of that coordination of care and reengineering. We as a company have spent a lot of time innovating in that area, looking at the preoperative experience – patient education and preparation, the intraoperative process – making the operation as efficient as possible, and coordination with post-surgical care. I think this will be a very important area of innovation for the device companies looking forward."***
>
> - ***Jeffrey Binder, Biomet***

Redefining Industry's Role

It is even more important now for Manufacturers to show benefits beyond just the individual product, such as how their product may improve or fit within care processes, through wraparound services and educational materials for physicians and patients. Innovation should no longer be siloed from the context of care, and manufacturers should focus their efforts on creating clinical solutions rather than single innovations.

To do this, providers, payers and others will need to open their doors to new partnerships and relationships with industry. Manufacturers are tremendously innovative and are willing to bring a wealth of knowledge to this new era of value-based care.

Improving Quality Measures Through A Multi-Sector Discussion

Finally, there must be adequate safeguards within bundled payments to encourage physicians to provide appropriate care to patients – matching the right therapy, to the right person, at the

right time. Multi-sector agreement of standard quality metrics must be developed to create measures that can reflect a broader, more appropriate spectrum of outcomes.

Bundled payments are only one model in a larger trend toward paying for value. As providers become more experienced with risk-sharing, others are likely to become involved, leveraging already proven models and combining them with other value-based efforts, like Accountable Care Organizations.

> ***"To have a health plan be in charge of [developing the kind of metrics we all want to have] won't work. We need everyone in the room; we need to be able to objectively talk about things."***
>
> - ***Steve Spaulding, Arkansas Blue Cross Blue Shield***

It is more important now than ever for the health care community to focus its effort on understanding how to do bundle payments right, and in a way that allows for continued and improved patient access to innovation. This requires continued study on how best to implement them, in what disease areas they work best, and how programs can make room for innovative care.

APPENDIX

Innovation in an Era of Payment Reform: How Will Bundled Payments Impact Innovation?

July 10, 2014

The Pew Conference Center, Washington, DC

List of Expert Roundtable Participants:

Deirdre Baggot, Vice President, The Camden Group; Expert Panel Reviewer, CMMI

Jeffrey Binder, President & CEO, Biomet

Molly Burich, Senior Manager, Government Affairs – Reimbursement and Policy, Otsuka Pharmaceuticals

Trisha Frick, Assistant Director of Managed Care Contracting, John Hopkins Healthcare LLC

Ryan Hohman, JD, Managing Director, Policy & Public Affairs, Friends of Cancer Research

Bob Ihrie, JD, Senior Vice President, Compensation & Benefits, Lowe's

Juan Reyna, MD, Urologist, San Antonio, TX; President, LUGPA Integrate Practices/Comprehensive Care

Steve Spaulding, Senior Vice President, Enterprise Networks, Arkansas BCBS

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