EDITORIAL

# Synchronization of Coverage, Benefits, and Payment to Drive Innovation

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## ABSTRACT

More than 35% of Medicare beneficiaries receive care from providers operating under some form of shared savings/risk type of pay-for-performance incentive. Implementation of payment reform without a corresponding change to coverage, benefit, and other payment requirements, however, creates conflicting incentives that may nullify the intended aim of payment reform: to improve health outcomes, while saving costs. If related policies do not evolve to align with payment reform, those entities contracted to receive new bundled payments, such as hospitals or physician groups, will only be able to redesign care to the extent that care meets the myriad of related payment policy requirements. Shifting greater medical management authority from payers to entities managing the payment bundles is a gradual process, as the experience of commercial payers proves. Transitioning the responsibility for modifying coverage, benefit, and payment requirements from CMS to principal accountable bundlers (PABs) will depend on the PAB's degree of financial risk sharing as well as scope of the episode.


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More than 35% of the nearly 50 million Medicare beneficiaries in 2013 received care from providers operating under some form of shared savings/risk type of pay-for-performance incentive. This statistic reflects more than 14.4 million beneficiaries in Medicare Advantage (MA) plans in 2013,[1] plans which are reimbursed paid using an annual capitation rate. It also includes 4.4 million beneficiaries in 2013 who are attributed to 252 Medicare accountable care organizations (ACOs) under the Medicare Shared Savings Program (MSSP),[2] which are paid using a combination of fee-for-service and shared savings or losses. In October 2013, additional beneficiaries began receiving care from providers participating in the Centers for Medicare & Medicaid Innovation's (CMMI's) Bundled Payment for Care Improvement Initiative (BPCI).[3] Under BPCI, awardees will be sharing financial risk with CMS for selected episodes of care.



CMS is incentivizing providers through payment reform to redesign healthcare services to improve health outcomes while saving costs. However, implementation of payment reform without a corresponding change to coverage, benefit, and other payment requirements creates conflicting incentives that may nullify the intended aims of payment reform.

To date, providers working under MA,[4] MSSP,[5] and the BPCI[6] must comply with 3 types of CMS policies. These policies are core to the medical management of patients: (i) coverage policies under Original Medicare Part A and Part B (eg, national and local coverage determinations[7]); (ii) Medicare benefit policies[8] (eg, hospital services, physician services, home healthcare, durable medical equipment, telehealth benefit[9]); and (iii) other payment policy requirements tied to payment systems for particular sites of care (eg, prior 3-day inpatient stay for covered skilled nursing facility services, 3-hour therapy inpatient rehabilitation rule). Interestingly, while traditional payment methodologies that are tied to the site of service are rapidly changing to allow for more innovative approaches—such as payment by episode of care, which

permits patients to receive treatments at multiple sites of service for 1 bundled payment—these 3 principles of coverage remain static.

Failure to evolve coverage, benefit, and payment policy requirements as payment methods change is likely to impede the ability of payment reform to reach maximum quality, efficiency, and innovation in care. If related policies do not evolve to align with payment reform, those entities contracted to receive new bundled payments, here referred to as principal accountable bundlers (PABs), are only able to redesign care to the extent that care meets the myriad of related payment policy requirements. PABs may be hospitals, physician groups, post-acute providers or third party entities who are in a position to financially and clinically oversee an episode of care. As shown in **Figure 1**, coverage and benefit mechanisms that were designed to support original payment models must be reconfigured to be in synch with new pay-for-performance paradigms.

As a general rule, Medicare requires entities participating in payment reform initiatives such as MSSP[10] and BCPI[11] to have processes in place that document and support adherence to evidence-based medicine payment initiatives. The intent is to ensure that efforts to redesign care actually result in clinically effective care. Tensions arise, however, when new payment incentives conflict with traditional coverage and benefit policies that have not changed. For instance, based on review of clinical evidence, a PAB's medical leadership team may find that although a particular medical innovation is reasonable and medically appropriate for its patient population when provided following the medical team's clinical pathway the service cannot be offered because it: (i) is not covered by Medicare; (ii) is not a Medicare benefit; or (iii) does not comply with a payment policy requirement. The net result is an unintentional stifling of innovation, not due to payment concerns, but because coverage and benefits are not synchronized to cooperate with the change in payment to allow an alternative treatment without roadblocks to payment.

A case in point is CMS's recent negative response to public requests to convert coverage of innovative remote access technologies (eg, telemonitoring, Web-based technologies, nurse hotlines, and other similar services) from the status of supplemental benefit to a basic benefit because CMS does not have the authority "to define Part C basic benefits as being broader or different than the Parts A and B benefits provided under original Medicare."[12]

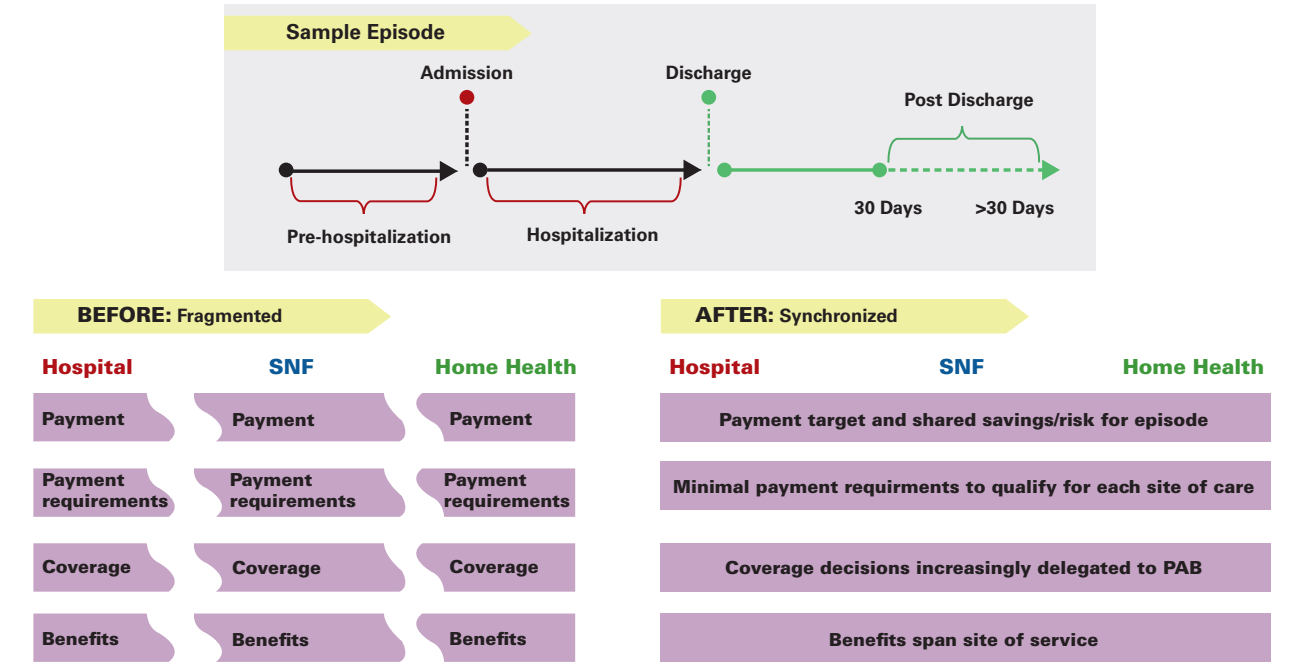
CMS has experience modifying payment requirements and coverage policies to support more bundled methods of payment, but to date, the approach has been ad hoc. Some examples include developing customized waivers for each payment model, and reviewing each request for a new supplemental benefit in the MA program. With new payment reforms emerging, a one-by-one review approach will soon become unwieldy, and implementation of payment reforms will be delayed. What's more, an unintended consequence of an ad hoc approach is that it often lacks transparency. For example, little is known about the waivers requested and offered under MSSP and BPCI.[13] It is an opportune time for CMS to adopt a more systematic and transparent approach to modifying coverage and benefit constructs to support the goals of payment reform.

As we will see, most coverage, benefit, and payment policy decisions are currently made centrally by CMS or regionally by local Medicare Administrative contractors, while decisions on how to spend the "bundle" are made by the PABs. The failure to delegate decision making to PABs regarding policies that are core to medical management is understandable in these early stages of payment reform, since current bundled arrangements with either Medicare or commercial payers include only limited financial risk for most PABs.[14,15] As payment reform moves ahead and PABs assume more financial risk, they will also want more authority to redesign all aspects of care; they will, for example, want to take on a greater role in designing all policies that impact medical management.[15]

In our recommendations below about how we believe the path forward should develop, we note that sharing more authority with PABs does not mean abandoning all existing coverage, benefit, and payment policies, but rather allowing PABs to modify these policies when they meet the conditions designed to ensure beneficiary protections. Examples of such conditions might include: (i) requiring PABs to meet baseline performance thresholds; (ii) having evidence-based decision-making processes in place, including a consensus-based approach by the PAB's medical leadership team, accompanied by ongoing evaluation mechanisms; (iii) ensuring transparency of these processes and policy modifications to providers and patients; (iv) establishing opportunities for appeal; and (v) using patient-centric decision-making tools (eg, shared decision-making tools) to ensure that patients are empowered to make informed decisions. If the PAB meets these conditions, CMS would not necessarily be required to approve every policy modification, but could transition to a role of monitoring performance and enforcement of these conditions.

In order to create a plan for synchronicity, it is helpful to review CMS's past efforts to adapt coverage, benefit, and payment policies to payment innovation. The discussion begins with a review of Medicare coverage policies.

**Figure 1.** Synchronizing Coverage and Benefits With Payment Reform




PAB indicates principal accountable bundler; SNF, skilled nursing facility.

We then provide an examination of CMS's experience with MA, the BPCI, and the introduction of the inpatient rehabilitation facility prospective payment system. We conclude with recommendations to guide steps forward, illustrated with examples from private payers who are facing similar challenges.

## Targets and Criteria for Medicare Coverage Policies

CMS focuses most of its attention on developing formal coverage policies for items and services that are likely to have a major impact on quality, safety, and the government budget. Although many items and services do not reach this level of attention, CMS is tasked with meeting the statutory requirement for Medicare services that "[n]o payment may be made under Part A or Part B for any expenses incurred for items or services, which...are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[16] Notably, this language has never been amended, or interpreted through public rulemaking.[17,18]

CMS determines what is reasonable and necessary based on whether there is "adequate evidence to conclude that the item or service improves health outcomes."[19,20] CMS ranks the quality of clinical studies based on numerous, coherent, and sensible criteria that help assess the reliability of the data generated.[21] When there is no specific coverage policy, a local Medicare Administrative Contractor (MAC) may remain silent or may decide to cover the service or item on a case-by-case basis.

## Coverage and Benefits Under Medicare Advantage

The MA program, formerly Medicare + Choice, was designed to give CMS an alternative way to provide services for patients who were willing to forgo some flexibility in selecting providers to get, in return, improved benefits and lower costs.[22] Commercial payers sponsor MA plans and assume the insurance risk under a capitated payment system for the services offered to their Medicare enrollees.

CMS requires that Medicare Advantage Organizations (MAOs) "provide coverage of...all services that are covered by Part A and Part B of Medicare…and that are available to beneficiaries residing in the plan's service area."[23] By the same token, if a service or item is explicitly not covered under Medicare Parts A or B, then it is also not covered under MA. For example, in a recent update to the Medicare Managed Care Manual, CMS notes, "An MA plan may not offer home health coverage or home health services beyond that covered by Original Medicare, if the Home Health Agency manual has classified those additional services as not covered by Original Medicare because they are not considered medically nec-

essary."[24] The Home Health Benefit Manual interprets the statutory requirement[25] that a Medicare beneficiary must be homebound to qualify for home healthcre.[26] Therefore, an MA plan cannot offer home healthcare to patients who are not homebound.

Additionally, MA plans may not add prerequisites to covered services. For example, if an MA plan wants to implement step therapy for a covered Part B drug as an approach to improving quality and saving costs, it would not be allowed to do so if step therapy is not also a requirement under Original Medicare.[27] CMS requires enrollees in MA plans to have, at a minimum, equal access to items and services covered by Original Medicare in their service area.[28]

For services or items on which CMS is silent (ie, where there is no Medicare national or local coverage determination), an MAO may choose to adopt the coverage policy of another MAO in its service area or make its own coverage determination. If an MAO makes its own coverage determination, it must provide its rationale using an objective, evidence-based process based on authoritative evidence.[29]

When an MAO would like to cover services beyond those covered under Original Medicare, the MAO must meet CMS conditions for "supplemental benefits."[30] Each supplemental benefit must be additional to the benefit covered by Original Medicare, be medically necessary, and must result in the plan incurring medical costs.[31] Examples of supplemental benefits include services such as additional inpatient hospital days (acute or psychiatric); waiver of the Medicare payment policy that requires a qualifying hospital stay of 72 hours (the 3-day rule) before skilled nursing coverage is available; availability of Medicare Part B; drugs and nursing services in the home and other Part D drugs as a bundled service.[32]

In recent years, CMS has been expanding the list of supplemental benefits. Some examples of services are certain counseling programs for mental health conditions; in-home safety assessment by qualified health providers; enhanced disease management; post discharge in-home medication reconciliation; readmission prevention services; telemonitoring services; and Web- and telephone-based technologies to help diagnose and treat some conditions.[33]

For CMS to approve each supplemental benefit, the benefit must meet certain requirements—telemedicine should supplement and not replace face-to-face visits, for example, and all allied health professionals involved in providing care must be licensed and certified. CMS reviews and approves each supplemental benefit annually as part of the plan bidding process.

Along with defining eligible supplemental benefits, CMS defines services that are ineligible. For example, stand-alone brain training/memory fitness is ineligible as a supplemental benefit because according to CMS, no conclusive evidence proves that any such services improve memory or brain function. Therefore, these services are not accepted clinical treatment modalities.[34]

The criteria CMS uses to differentiate between eligible and ineligible supplemental benefits are not transparent. CMS "encourages plans to offer supplemental benefits to enrollees that are of value and based on sound medical practice,"[35] and offers MA plans the opportunity to comment on changes to supplemental benefits. In the end, however, CMS retains the authority to determine what is considered an eligible new "health benefit." Often, it provides limited documentation explaining its decision. While MA plans are paid on the basis of a broad bundle of services, they have limited flexibility to cover new services or modify existing coverage or benefit policies. CMS provides tight guidelines on what is eligible as a supplemental benefit, with minimal public discussion of its decisions.

## Coverage and Benefits Under Original Medicare Payment Reform Initiatives

In contrast to the MA program in which Medicare benefits are provided through commercial insurance, the BPCI and MSSP Initiatives are part of Original Medicare. They are, therefore, directly insured by CMS. Under these initiatives, CMS plans to transfer a portion of the financial risk to PABs through shared savings and discount arrangements.

In the MSSP, CMS plans to eventually pay some participating providers a fully capitated payment similar to MA plans. In all cases, however, PABs remain bound to the established coverage requirements under Medicare Parts A and B.[36,37]

Under the BPCI initiative, in Model 1 (acute inpatient; retrospective), Model 2 (acute inpatient and post acute care; retrospective), and Model 3 (post acute care; retrospective), Medicare pays for all services, including waived services, using fee-for-service. In return, CMS generates savings based on prearranged discounted episode bundled payment amounts. Under BPCI Model 4 (Acute inpatient; prospective), providers pay for the all services, including waived services, by drawing on their prospectively determined episode payment amount.

In the BPCI initiative as in the MA program, CMS reviews and approves (or not) each request for a waiver of Medicare payment rules, referred to as "payment policy waivers."[38] CMS's review criteria include an assessment of whether the waived requirement is integral to care redesign, leads to program success, and has the potential to

generate internal cost savings. Table 1 shows an illustrative list of waivers that BPCI applicants requested compared with waivers that already exist in the MA program, as well as those CMS has officially approved for all BPCI awardees. For example, a BPCI applicant requested a waiver of the "3-hour rule" for inpatient rehabilitation facilities (IRFs). The 3-hour rule states that IRF patients generally require 3 hours of therapy for 5 days per week, unless the patient is unable to tolerate that level of therapy. Any patient in a post acute setting who is not able to tolerate 3 daily hours of therapy must be transferred to a sub-acute care facility. According to the applicant, this requirement may lead to potentially unnecessary readmissions to a skilled nursing facility, especially when the patient's fragility is only temporary.[39]

Table 2 demonstrates that there is substantial variability in CMS's payment policy waivers across payment models. CMS granted few waivers in the BPCI initiative. Those waivers that were granted may be attached to other requirements (eg, patients transferred from hospitals must go to high-quality SAFs).[40] Examples of inconsistencies include: (i) the qualifying 72-hour rule before transfer to a covered skilled-nursing stay is waived for MA plans but waived only with the conditions in the BPCI initiative; (ii) pre-surgery home safety visits are waived for MA plans, while post discharge home visits are waived in the BPCI initiative; (iii) CMS does not waive conditions for Medicare's traditional telehealth benefit for MA plans, but does expand the telehealth benefit for BPCI awardees; (iv) CMS allows some remote monitoring in MA plans, but not for BPCI awardees. CMS has not had a public discussion of the rationale behind these differing decisions.

This lack of public discussion contrasts sharply with the way CMS approached its 2003 change in payment methodology for IRFs from cost basis to prospective payment (IRF-PPS) and the subsequent revisions to the IRF coverage requirements. CMS made those changes through a multiyear rule making process that vetted the recommendations of a CMS internal working group through opportunities for public comment.[41]

As a result of the rulemaking process, CMS deleted the coverage guidance previously published in HCFAR 85-2-1 "to reflect changes that have occurred in medical practice during the past 25 years and the implementation of the IRF-PPS."[42]

## Summary

CMS has used various approaches to adapting coverage, benefit, or payment requirements in response to changes in payment methods. Examples are presented in Table 2.

In the MA program, which bases reimbursement on a capitated rate rather than on a fee-for-service amount, CMS has created supplemental benefits. For BPCI awardees, CMS has not relaxed coverage policy requirements. It has, however, granted payment policy waivers to remove certain site-specific payment requirements. When prospective payment was introduced for IRFs, CMS revised requirements for covered admissions through rule making. That is, to introduce a single policy change, CMS has engaged multiple mechanisms. For example, CMS relaxed the requirement to have a qualifying hospital stay of 72 hours before covering a skilled nursing admission as a "supplementary benefit" in the MA program, and as a payment policy waiver in the BPCI initiative.

## A Path Forward

Shifting greater medical management authority from CMS to PABs is a gradual process, as shown by the experience of commercial payers who have partnered with ACOs. For instance, Fairview Health Services in Minnesota, which has been working with accountable care models for over 10 years, is continuing to take on more duties around care management that were traditionally assumed by health plans.[43] One of the many lessons learned from Premier's Partnership for Care Transformation (PACT Population Health Collaboration is the importance of creating new divisions of labor between providers and payers around responsibilities for care management.[44]

In 2010, the experiment of UnitedHealthcare (UHC) that provided an upfront "episode payment" for the treatment of selected cancers to medical oncologists, rather than fee-for-service reimbursement, demonstrated that payment, coverage, and benefit silos can be effectively synchronized to deliver better health outcomes at a reasonable cost within a system of care.[45,46] In this case, a team of oncologists acted as the PAB, evaluating clinically equivalent regimens and developing recommendations for coverage based on cost. They also incorporated the flexibility to accommodate other treatment regimens based on a patient's unique profile. The net effect was to disconnect the income of the oncologist from the sale and use of specific drugs, while covering the most effective treatment regimens in order to improve patient outcomes.[46] Both the American Society of Clinical Oncology and the American Cancer Society–Cancer Action Network issued positive statements about the new program, because at a minimum, it allowed UHC to test whether or not the change in payment methodology actually influenced the

**Table 1.** Comparison of Waivers Under BPCI and MA Supplemental Benefits

| Potential New Coverage Benefit | Medicare Advantage-Allowed Supplemental Benefit[a] | Example of Bundled Payments for Care Improvement Applicant Request[b] | CMS-Approved Waivers for Bundled Payments for Care Improvement[c] |
|---|---|---|---|
| **Waiver of qualifying hospital stay of 72 hours before covered skilled nursing facility stay** | Approved | Requested | Approved for Model 2 only. Two quality assurance conditions are associated with this waiver.<br><br>**Awardee Eligibility:** Waiver available to awardees that partner with high-quality SNFs such that the majority of their partner network are SNFs rated 3 stars or better under the 5-Star Quality Rating system of Nursing Home Compare.<br><br>**Monitoring:** Review of claims data to verify the majority of the Model 2 beneficiaries who left the hospital before a 3-day minimum length and received SNF services were cared for at SNFs rated 3 stars or better. |
| **Waiver of the "amount, frequency, and duration" limit on home health services.** | Not waived | Requested | Not waived |
| **Waiver of the homebound requirement for home health services** | Not waived | Requested | Not waived |
| **Waiver for certain home visits** | Allow in-home safety assessment as preadmission service for patients scheduled to undergo surgery.<br><br>Provided to beneficiaries who do not qualify for an in-home safety assessment under Original Medicare's home health benefit. | Requested | If home healthcare services are not sufficient or appropriate (for example, in cases where the patient is not "homebound"), Medicare will pay for a post discharge home visit, described in a newly created code.<br><br>CMS will waive the direct supervision requirement under 42 CFR 410.26(b)(5) so that an employee of a physician could furnish the service to the beneficiary in his/her home under general supervision of a physician.<br><br>New HCPCS G-Code will be created specifically for BPCI use with specific periodicity requirements (for 30-, 60-, and 90-day episodes, 1, 2, and 3 times per episode, respectively). |
| **Waiver of the "3- hour rule" for Inpatient Rehabilitation Facilities[d]** | Not waived | Requested | Not waived |
| **Telehealth** | No change in original Medicare telehealth services benefit.<br><br>May provide remote access technologies (including Web- and telephone-based technologies) to monitor enrollees with specific health conditions (eg, hypertension or chronic heart failure) when several conditions are met.<br><br>Supplement to existing physician-patient relationship. | Not requested | Applicable to Models 2 and 3 only.<br><br>Currently, telehealth services are limited to originating sites located in Health Professional Shortage Areas and rural areas. This waiver expands the availability of telehealth services and allows Medicare to make payments for covered telehealth services furnished to beneficiaries in originating sites located in urban areas. All other existing telehealth requirements will still be in place. |

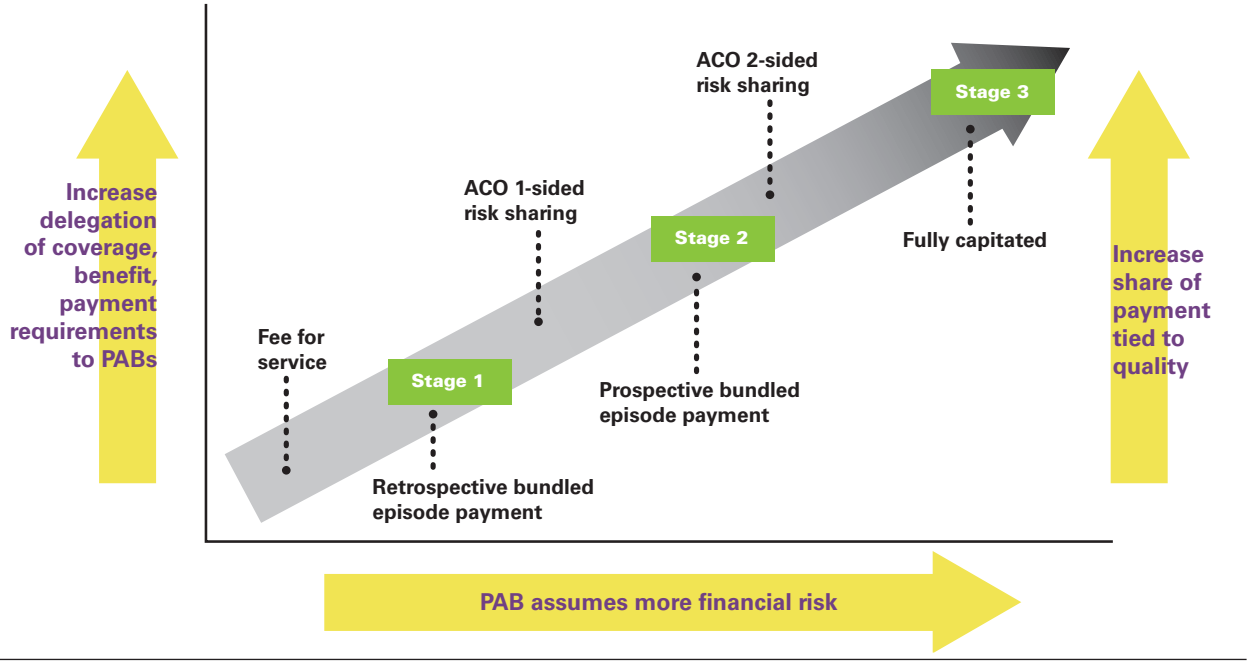
[a]CMS. Pub 100-16. Medicare Managed Care Manual. Chapter 4 – Benefits and Beneficiary Protections. §30.2.3. June 2013.
[b]American Hospital Association. "Reforms to Medicare Payment for Post Acute Care". Comment Letter Addressed to the House Ways and Means Committee and Senate Finance Committee. August 19, 2013. http://www.aha.org/advocacy-issues/letter/2013/130819-let-aha-senate-finance.pdf accessed 8/22/13; and Association of American Medical Colleges. Testimony to House Ways and Means and Energy and Commerce Committees. April 15, 2013.
[c]CMS. "Bundled Payments for Care Improvement: Candidate Awardee Webinar Series: Key BPCI Models 2-4 Policies (Other Than Payment Policies)." May 16, 2013. See also CMS. "Webinar Series: Bundled Payments for Care Improvement: Winter Open Period 2014 for Models 2,3,4." March 4, 2014.
[d]CMS. Pub 100-2. Benefit Policy Manual. Chapter 1. §110.4.3.

**Table 2.** CMS Criteria for Changes in Coverage or Benefits When Payment Methods Change

| | |
|---|---|
| **Medicare Advantage Program** | Each supplemental benefit must be additional to the benefit covered by Original Medicare, be medically necessary, and must result in the plan incurring medical costs.[a] "CMS encourages plans to offer supplemental benefits to enrollees that are of value and based on sound medical practice."[d] |
| **Bundled Payment for Care Improvement** | A payment policy waiver may be granted when the waived requirement is integral to care redesign, leads to program success, and has the potential to generate internal cost savings.[c] |
| **Inpatient Rehabilitation Facility** | Changes in coverage conditions should reflect changes that have occurred in medical practice.[d] |

[a]CMS. Pub 100-16. Medicare Managed Care Manual. Chapter 4–Benefits and Beneficiary Protections. June 2013. §30.1.
[b]Moon, D. Memorandum to All Medicare Advantage Organizations, and 1876 Cost Contractors. "Contract Year 2014 Medicare Advantage Bid Review and Operaions Guidance." April 17, 2013. P. 10.
[c]Association of American Medical Colleges. Testimony to House Ways and Means and Energy and Commerce Committees. April 15, 2013.
[d]Federal Register 74(86) August 7, 2009. p. 39788.

**Figure 2.** Delegating Medical Management Responsibility to Principal Account Bundlers




ACO indicates accountable care organization; PAB, principal account bundler.

drugs that physicians prescribed for their patients.[47] UHC undertook several measures to ensure appropriate patient care. For example, a team of oncologists developed evidence-based clinical pathways that guided patient care. Only when pathways were deemed to be clinically equivalent was the least expensive regimen selected.[48]

As shown in Figure 2, transitioning the role of medical management from CMS to PABs, including the ability to modify coverage, benefits, and payment requirements, can be viewed as a continuum that includes 3 main stages. The stages are tied to the PAB's degree of financial risk sharing, as well as the scope of the episode. PABs assuming minimal financial risk would fall under Stage 1 and receive limited delegated authority focused primarily on modifications of payment requirements directly relevant to the payment methods being replaced (eg, prior 3-day inpatient stay for covered skilled nursing facility services; 3-hour therapy inpatient rehabilitation rule). PABs assuming greater financial risk, (eg, prospective bundled payments for selected patient conditions) would fall under Stage 2 and would have the delegated authority to modify not only payment policy requirements but also coverage policies for the patient conditions they are targeting. PABs assuming full financial risk for a comprehen-

sive set of clinical conditions would fall underStage 3 and would be delegated even more authority, allowing them to modify benefit policies. Except for changes in benefit policies, these stages, for the most part, could be implemented without legislation and in ways that satisfy the statute to provide reasonable and medically necessary care.

National and local coverage policies would be the starting point for any explicit coverage policy for a PAB. In Stage 2, however, the PAB would be able to expand/limit coverage or even cover otherwise noncovered services (by overturning a local or national noncoverage policy), allowing more opportunities for medical innovation. For example, based on an evidence- and consensus-based approach, the medical leadership team could choose to cover an otherwise noncovered innovative diagnostic or treatment service for their population. The PAB could target provision of the service within a carefully defined clinical pathway.

## CONCLUSION

Moving away from volume-based fee-for-service payment methods to value-based payments is widely recognized by many as a way to incentivize patient-centric, high-quality, innovative, and efficient care in the Medicare program. Making the unit of payment broader and tying payments to performance measures is helpful for setting the direction for health- system change, but it will not be sufficient. The myriad of payment, coverage, and benefit policies—and the processes for establishing them—were created during the era of payment silos. They now will need to be revisited and redesigned if we are to fully realize the objectives of payment reform. As in the commercial payer world, how fast this occurs will depend on the CMS's appetite for change, the PAB's ability to take on these new responsibilities, and Congressional action to support change.

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