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Table of Contents

The Shape of Provider-Based Status to Come: The Impact of the Bipartisan Budget Act and the March Toward Site Neutral Payment

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On November 2, 2015, President Barack Obama signed the Bipartisan Budget Act of 2015 (Act) into law.[1] While the legislation itself—principally an effort to raise the federal debt ceiling and set federal spending—came as no surprise, its inclusion of a significant limitation in the way Medicare will reimburse hospitals for outpatient services furnished in newly created or acquired off-campus departments caught many off guard.

Beginning January 1, 2017, off-campus hospital outpatient departments that did not bill for services under the Medicare Outpatient Prospective Payment System (OPPS) prior to the date of enactment of the Act will no longer be eligible for reimbursement under OPPS. Instead, these departments will be paid under an applicable Medicare Part B payment system, such as the Physician Fee Schedule (PFS) or Ambulatory Surgical Center (ASC) payment system. These systems typically provide for lower payment rates for the same services.

The fact that a change in Medicare payment for hospital outpatient departments was made is not altogether surprising. For many years, government watchdogs have expressed concern regarding the propriety of increased payment based solely on the site of service. However, the scope of the changes made by the Act and the suddenness of their arrival surprised many in the health care industry. The purpose of this article is to provide some background on the issues at play, explain the effect of the Act on Medicare payment for services provided in off-campus hospital outpatient departments, and highlight some of the major issues left unresolved by the Act.

A Brief History of Provider-Based Status

From the beginning of the Medicare program, hospitals have owned other facilities that are administratively integrated and operated as subordinate

units. Historically, the agencies tasked with administering the Medicare program permitted these subordinate facilities to be considered "provider-based" to the hospitals in order to accommodate their financial integration (i.e., to allow hospitals to reflect shared overhead costs in their cost reports).[2]

The transition of the Medicare program from a retrospective, cost-based payment system to a prospective payment system created a financial incentive for hospitals to designate subordinate facilities as provider-based. Under the retrospective, cost-based payment system, the Medicare program benefitted from the economies of scale achieved by hospitals that operated provider-based facilities. With the advent of the inpatient prospective payment system in 1983, however, hospitals had an opportunity to increase Medicare revenue by shifting overhead costs associated with hospital inpatient services (which costs were intended to be covered by the prospective payment system payment) to provider-based departments, which at the time were still subject to a retrospective, cost-based payment system. The result, in the eyes of the Health Care Financing Administration (HCFA), was an increase in Medicare payments with no commensurate benefit to the Medicare program or beneficiaries.[3]

Other developments in payment policy resulted in the total Medicare payment due to a hospital for services rendered in its provider-based department often exceeding (and in some cases, far exceeding) the payment that would have been due if the department were operated as a freestanding entity. Medicare payment for services furnished in a hospital outpatient department generally consists of both a facility payment to the hospital under the OPPS and a payment for the professional services of a physician under the PFS. The total of these two payments is typically greater than the payment for comparable services rendered in, for example, a freestanding physician office, where a separate facility fee is not payable, as the fee for the professional services under the PFS is intended to include a practice overhead expense component. In addition to a larger payment from the Medicare program, the provision of services in a hospital outpatient department often results in an increase in beneficiaries' out-of-pocket expenses, as beneficiaries are required to pay coinsurance for both the facility and professional charges.[4]

Citing a significant increase in the number of provider-based facilities and the need for the Medicare program to act as a prudent purchaser of services, HCFA issued a program memorandum in August 1996 that specified criteria that must be met in order for a hospital or other main provider to bill for services of a facility as if the facility was provider-based.[5] In April 2000, HCFA finalized regulations setting forth these criteria in greater detail.[6] Among the criteria were requirements that the main provider and the provider-based facility operate under the same state license, the provider-based facility operate under the ownership and control of the main provider, and the provider-based facility be located in the immediate vicinity of the main provider. The regula-

tions also included an explicit application requirement for all facilities seeking provider-based status: subject to certain limited exceptions, main providers were required to apply for and receive a provider-based determination for their facilities prior to billing for services in those facilities as provider-based.

In August 2002, the agency, now operating as the Centers for Medicare & Medicaid Services (CMS), issued another final rule in which it revised the provider-based regulations in the wake of new legislation and industry reaction.[7] Chief among the revisions was the replacement of the application requirement with a voluntary attestation process. The resulting regulations, which are set forth in Section 413.65 of Title 42 of the Code of Federal Regulations, became effective October 1, 2002, and have been largely unchanged since that time.

The provider-based regulations impose a wide range of requirements, almost all of which are geared toward ensuring that the provider-based facility is meaningfully integrated with the hospital or main provider. For example, the provider-based facility and the main provider must be operated under the same license (except where state law does not permit as much), the clinical services of the provider-based facility and the main provider must be integrated, the financial operations of the provider-based facility and the main provider must be fully integrated, and the provider-based facility must be held out to the public and other payers as a part of the main provider. Additional requirements apply to off-campus facilities, reflecting a concern that with greater distance comes greater challenges to *bona fide* integration.

Renewed Interest in Provider-Based Reimbursement

Notwithstanding the rigor of the standards imposed by the provider-based regulations, provider-based reimbursement—or more precisely, the difference between total Medicare payment for services rendered in a provider-based department and Medicare payment for the same services rendered in a freestanding facility—has continued to draw the attention of government agencies and other interested parties. This interest is hardly surprising given the well-documented proliferation of provider-based departments, the migration of services from freestanding offices to provider-based departments, and the attendant increase in Medicare spending. One recent report found that while total Part B spending grew by an average annual rate of 5.8% from 2007 through 2013, Medicare expenditures for hospital outpatient department services increased at an average annual rate of approximately 8.3% during the same period.[8]

The Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established to advise Congress on issues affecting the Medicare program, has issued several reports in which it has recommended that action be taken to reduce the difference in Medicare payment. For example, in its March 2012 report to Congress, MedPAC recommended that Congress direct the U.S. Department of Health and Human Services (HHS) to reduce payment rates for evaluation and management office visits provided in hospital outpatient departments so that the total payment rates for these visits are the same whether the service is provided in an outpatient department or a physician office.[9] In developing this recommendation, MedPAC expressed its concern that such a change could have the effect of reducing access for low-income patients, in that some hospitals that provide ambulatory services for such patients might experience significant reductions in Medicare revenue. For this reason, MedPAC recommended that revenue losses from this change in policy be limited to 2% of overall Medicare revenue for hospitals that serve a relatively large share of low-income patients.[10] In a June 2013 report, MedPAC reiterated its recommendation regarding evaluation and management services, and also suggested that Congress could eliminate or reduce payment differences for services such as cardiac imaging and surgical services.[11]

Most recently, MedPAC reiterated its recommendation that setting-dependent differences in payment rates for certain ambulatory payment classifications be reduced or eliminated in a March 2015 report to Congress.[12] In the 2015 report, MedPAC concluded that the growth in outpatient services is in part a reflection of the incentive hospitals have to shift patients to higher cost sites of care.[13] MedPAC took aim at evaluation and management services—noting, for example, that the Medicare program spent approximately $1 billion more in 2009 and $1.5 billion more in 2013 than it would have if payment rates for evaluation and management services were the same in hospital outpatient department and freestanding offices[14]—but did not spare other services, reemphasizing an earlier recommendation that hospital outpatient department payment rates for 66 ambulatory payment classification codes be reduced.[15]

The HHS Office of Inspector General (OIG) also has taken an interest in the issue. In April 2014, OIG issued a report entitled, "Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates."[16] In the report, which was completed in response to a congressional request for an assessment of the impact of providing surgical services in an ASC as opposed to other outpatient settings, OIG estimated savings to the Medicare program of $7 to $15 billion for 2012 through 2017 if CMS reduced hospital outpatient department payment rates for ASC-approved procedures to ASC payment levels for procedures performed on beneficiaries with low-risk and no-risk clinical needs.[17] In addition to the April 2014 report, OIG has highlighted compliance with the provider-based regulations and the comparison of provider-based and freestanding clinics as areas of focus in several of its recent annual work plans.[18]

In addition to these reports and recommendations, several recent enforcement efforts evince government interest in ensuring compliance with the provider-based regulations,

perhaps in acknowledgment of the significance of the financial benefit that is often associated with provider-based status. In October 2014, the U.S. Department of Justice (DOJ) announced a $3.37 million settlement with a New York hospital to resolve federal False Claims Act liability stemming from self-reported non-compliance with the provider-based regulations involving the hospital's hyperbaric oxygen therapy services program.[19] One news outlet reported a $2.635 million settlement with DOJ in 2015 for what appears to have been a similar self-reported matter involving a hospital system in Michigan.[20] In addition to these settlements, many commentators have remarked on the increased scrutiny applied by CMS in its review of provider-based attestations over the past few years, particularly with respect to arrangements involving shared space.[21]

The Bipartisan Budget Act of 2015

Against this backdrop, the Act was passed by Congress and signed into law on November 2, 2015. Section 603, entitled "Treatment of Off-Campus Outpatient Departments of a Provider," is the portion of the Act that, in approximately 500 words, makes significant changes in the way new, off-campus hospital outpatient departments will be reimbursed by the Medicare program. The changes made by Section 603 have been estimated by the Congressional Budget Office to result in savings of $9.3 billion to the federal government over the next 10 years.[22]

Section 603 of the Act amends Section 1833(t) of the Social Security Act, which governs Medicare payments for hospital outpatient department services, to add a new clause that excludes from the definition of covered services most items and services furnished on or after January 1, 2017, by an "off-campus outpatient department of a provider." The term "off-campus outpatient department of a provider" is defined by reference to the provider-based regulations to include a department of a provider that is not located on the provider's campus or within a 250-yard radius from a remote location of a hospital. Importantly, the Act excludes from the definition those departments that were billing Medicare for covered hospital outpatient department services furnished prior to the date of enactment. Thus, off-campus departments in operation prior to November 2, 2015, will receive "grandfathered" status and continue to be paid under the OPPS, but new off-campus departments will only be eligible for such reimbursement until January 1, 2017, at which time they will be paid under an applicable Part B payment system, such as the PFS or ASC payment system. In other words, new off-campus hospital outpatient departments will, beginning January 1, 2017, be paid at the same rate as if the departments were freestanding facilities unaffiliated with a hospital.

Several of the changes made by Section 603 are particularly noteworthy. First, the payment limitation does not apply to on-campus hospital departments (i.e., those departments that are located in the physical area immediately adjacent to, and in any event within a 250-yard radius of, the hospital's main buildings).[23] In addition, the payment limitation does not apply to certain other off-campus facilities that are required to meet the provider-based regulations, including remote locations of a hospital, satellite facilities, and provider-based rural health clinics. No change in payment to these facilities will occur as a result of the Act, even if they are established or acquired on or after January 1, 2017; the payment limitation applies solely to off-campus hospital outpatient departments.

Second, the scope of the grandfathering provision is limited and somewhat ambiguous. Section 603 shields from the payment limitation off-campus hospital outpatient departments that were "billing [as a hospital outpatient department] with respect to covered [hospital outpatient department] services furnished prior to the date of the enactment." No opportunity is given for hospitals to seek exceptions to this rule, nor does Section 603 include any allowance for rural or safety net hospitals, or for hospitals currently in the process of acquiring or creating a new off-campus department. It also is not entirely clear how the language applies to recently added off-campus departments. Consider, for example, the case of a hospital that added an off-campus outpatient department effective November 1, 2015, but did not see a Medicare patient until November 2, 2015 (or that saw a Medicare patient on November 1, 2015, but did not bill for services until November 2, 2015).

Third, the payment limitation will apply to all items and services rendered by new off-campus hospital outpatient departments, except for items and services furnished by a dedicated emergency department.[24] Not only does Section 603 limit payment for evaluation and management services, it also limits payment for procedures and surgical services. As described above, previous proposals and recommendations from MedPAC and OIG generally focused on reducing site-of-service payment differentials for a narrower range of services.

Fourth, Section 603 authorizes CMS to collect more detailed information from hospitals about their off-campus hospital outpatient departments. Specifically, Section 603 directs hospitals to provide to CMS such information as CMS requires to implement Section 603, which may include listing a code or modifier on claims for off-campus outpatient department services or reporting information about off-campus outpatient departments on enrollment forms. CMS may take this opportunity to require the reporting of information beyond that which is currently required (which includes listing off-campus departments as "practice locations" on Medicare enrollment applications and, beginning January 1, 2016, adding modifier "PO" to every Healthcare Common Procedure Coding System code for services furnished in off-campus departments).

Open Questions

Five hundred words is not enough to address the many questions that arise from a payment system shift as significant as that caused by Section 603 of the Act. CMS has indicated

that it will implement Section 603 of the Act through notice and comment rulemaking in 2016.[25] Many anticipate that these regulations will be made part of the annual OPPS rulemaking cycle, with a proposed rule issued in late June or early July, and a final rule in late October or early November. What follows is a brief discussion of some of the major questions that CMS may take up in the rulemaking process.

How Will CMS Identify Off-Campus Outpatient Departments?

It remains to be seen precisely how CMS will identify off-campus outpatient departments for purposes of implementing the payment changes made by Section 603. The statute does not speak to the issue, and there are several readily apparent options. For one, CMS could look to hospitals' enrollment files. Hospitals are required to identify all practice locations where the hospital provides services as part of the Medicare enrollment process. CMS also could identify off-campus outpatient departments by reference to the now required "PO" modifier on claims. Both approaches are unsatisfactory to a degree, in that a hospital's failure to take relatively simple administrative actions (i.e., updating its Medicare enrollment profile or properly appending a new modifier to its claims for services) would have outsized payment consequences. Another alternative would be to identify off-campus outpatient departments by reference to hospitals' cost reports.

Of course, CMS could develop an entirely new means of identifying off-campus outpatient departments pursuant to its authority under Section 603. While a return to a mandatory attestation process may not be workable (for providers and CMS alike), CMS could develop an attachment to Form CMS-855A that required disclosure of additional data regarding off-campus outpatient departments, along the lines of what it has done with respect to home health agencies and physician-owned hospitals.

What Exactly is an Off-Campus Outpatient Department?

The changes made by Section 603 bring the definition of "campus" to the forefront. The provider-based regulations define the term to mean "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."[26] Yet, many of the key phrases in this definition, including "main building," "immediately adjacent," and "strictly contiguous," are not specifically defined in the regu-

lations. Given the financial impact of whether an outpatient department is located on the "campus," the industry would benefit greatly from a clearer definition of the term.

May Grandfathered Departments Be Expanded? Repurposed? Relocated?

Section 603 leaves open many questions regarding the limits imposed on grandfathered off-campus outpatient departments. As patient needs change and physical plants age, hospitals will need to expand, repurpose, and relocate off-campus outpatient departments. Whether these actions jeopardize the grandfathered status of the departments is unclear.

With respect to the issue of expansion, Section 603 includes no specific limitation on grandfathered departments; rather, the exception simply requires that the department was billing with respect to covered outpatient department services furnished prior to the date of enactment. One could argue that the statutory language permits an expansion of services, provided that the expansion did not result in a change in location and did not result in a change in what the "department" is. One could make a similar argument regarding repurposing a grandfathered department, though such an argument would have to work around the idea that the repurposed department was not itself billing for services as of the date of enactment. Of course, CMS may take a different approach in the rulemaking process. For that reason, providers would be well-served to wait for regulatory guidance before making material changes to a grandfathered off-campus outpatient department.

Whether a grandfathered off-campus outpatient department may be relocated is another difficult question. The provider-based regulations define the term "department of a provider" to "comprise[] both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility."[27] In commentary to its 2002 final rule modifying the regulations, CMS stated: "We proposed this change because we believed it would help clarify that we would make determinations with respect to entities considered in their role as sources of health care services and not simply as physical locations."[28] In the view of the authors, these statements leave providers with an unsatisfying duality that would benefit from additional rulemaking. Going a step further, it is easy to imagine scenarios in which it would seem unfair and inconsistent with the policy goals of the Medicare program to penalize a provider with the loss of grandfathered status due to mere relocation. For example, consider the case of a grandfathered off-campus outpatient department that was required to relocate due to the expiration or termination of its lease.

Did Congress Miss the Mark?

Separate and apart from the question of how Section 603 of the Act will be implemented is the question of whether it really does what it was intended to do, or, more precisely, whether it addresses the concerns expressed by those who have been studying the issue. As described above, MedPAC and OIG recommendations generally focused on payment reductions for a narrower range of services. They also did not propose a grandfathering concept. In addition, they generally did not draw a distinction between services provided in on-campus and off-campus outpatient departments.

In December 2015, the Government Accountability Office (GAO) issued a report at the request of Senator Orrin Hatch (R-UT), Senator Mike Enzi (R-WY), and Representative Jim McDermott (D-WA) in which it concluded that, in order to stem the shift of services from lower paid freestanding settings to higher paid hospital outpatient department settings, Congress should direct HHS to equalize payment rates between settings for evaluation and management office visits.[29] While in some ways the GAO report came too late, it proposed a nuanced change similar to those previously recommended: a relatively narrow range of services, with no distinction between services on- and off-campus, and no grandfathering. In contrast, Section 603 preserves the ability of grandfathered facilities to continue being paid in the same manner that they have been, while shutting the door on OPPS reimbursement for virtually all items and services provided at newly created or acquired off-campus facilities. As described by one commentator, its solution is more hatchet than scalpel.[30]

Its lack of nuances aside, Section 603 is the law of the land. Given the many questions associated with its implementation, providers should monitor CMS activity on the subject of provider-based status closely and be on the lookout for rulemaking later this year.

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1 Pub. L. No. 114-74 (2015).
2 *See* 65 Fed. Reg. 18434, 18504 (Apr. 7, 2000) ("2000 Final Rule").
3 *See* 63 Fed. Reg. 47552, 47587-47588 (Sept. 18, 1998).
4 *Id.* at 47588.
5 *See* HCFA, Program Memorandum A-96-7 (Aug. 27, 1996). This Program Memorandum was later reissued, without substantive change, as Program Memorandum A-98-15 and Program Memorandum A-99-24. It also was incorporated in the Provider Reimbursement Manual, Part I, Transmittal 411, and the State Operations Manual, Transmittal 11.
6 *See* 2000 Final Rule.
7 *See* 67 Fed. Reg. 49982 (Aug. 1, 2002) ("2002 Final Rule").
8 U.S. Government Accountability Office, *Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, GAO-16-189 (Dec. 2015) ("2015 GAO Report").
9 MedPAC, *Report to the Congress: Medicare Payment Policy* (Mar. 2012).
10 *Id.* at 74.
11 MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2013).

12 MedPAC, *Report to the Congress: Medicare Payment Policy* (Mar. 2015).
13 *Id.* at 54.
14 *Id.*
15 *Id.* at 71. In its March 2014 report, MedPAC found that setting-dependent payment differences were not justified for 66 ambulatory payment classification codes on the basis that the codes met all or most of the following criteria: (1) the services are provided in a physician's office more than 50% of the time; (2) the services have minimal differences in packaging of supplies and ancillary services in the payment rates; (3) the services are infrequently provided in emergency departments; (4) the services occur when patient severity is no greater in hospital outpatient departments than in physician offices; and (5) the codes are not a 90-day global code in the PFS. *See MedPAC, Report to the Congress: Medicare Payment Policy* (Mar. 2014).
16 OIG, *Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, A-05-12-00020 (Apr. 2014).
17 *Id.* at ii.
18 *See* OIG, Work Plan for Fiscal Year 2014; OIG, Work Plan Fiscal Year 2015; OIG, Work Plan Fiscal Year 2016. In its work plan for fiscal year 2016, OIG indicated that it will determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing, as well as the extent to which provider-based facilities meet the requirements set forth in the provider-based regulations.
19 *See* DOJ Press Release, *Our Lady Of Lourdes Memorial Hospital Has Paid More Than $3.37 Million To Resolve Self-disclosed Billing Improprieties* (Oct. 16, 2014), *available at* www.justice.gov/usao-ndny/pr/our-lady-lourdes-memorial-hospital-has-paid-more-337-million-resolve-self-disclosed.
20 *See* AISHealth, *Provider-Based Rules Trigger 2nd Hospital Settlement; CMS Targets Shared Space*, Report on Medicare Compliance (Apr. 6, 2015), *available at* https://aishealth.com/archive/rmc040615-01.
21 *See, e.g.*, Emily W. G. Towey and Colin P. McCarthy, *The Risky Business of Co-Location Arrangements: What Hospitals and Other Providers Should Know*, AHLA Connections (Mar. 2015).
22 *See* Congressional Budget Office, *Estimate of the Budgetary Effects of H.R. 1314, the Bipartisan Budget Act of 2015, as Reported by the House Committee on Rules on October 27, 2015, available at* www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1314.pdf.
23 In a departure from prior CMS policy, Section 603 excludes from the definition of "off-campus outpatient department of a provider" those departments that are located in or within a 250-yard radius of a remote location of a hospital. In other words, by its terms, Section 603 permits a multi-campus hospital to add outpatient departments within 250 yards of the main buildings of any of its campuses (i.e., its remote locations) without loss of OPPS payment after December 31, 2016.
24 An earlier version of the legislation did not categorically exclude items and services furnished by a dedicated emergency department, instead excluding only emergency department services identified by HCPCS codes 99281 – 99285. However, as enacted, the Act excludes all items and services furnished by a dedicated emergency department, as that term is defined in 42 C.F.R. § 489.24(b).
25 *See* CMS, *Off-Campus Provider Based Department "PO" Modifier Frequently Asked Questions*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/PO-Modifier-FAQ-1-19-2016.pdf.
26 42 C.F.R. § 413.65(a)(2).
27 *Id.*
28 2002 Final Rule, 67 Fed. Reg. at 50080.
29 *See* 2015 GAO Report.
30 *See* Norman G. Tabler, Jr., *GAO Recommendations on Payment Reform: Too Little, Too Late?*, AHLA Weekly (Jan. 15, 2016).

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Chair's Column: "MIPS on the Move"

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In my introductory Chair's Column last quarter, I spoke of the excitement of taking the helm as Chair of the Regulation, Accreditation, and Payment Practice Group (RAP PG) at a time of fundamental sea changes in the way Medicare delivers and pays for services. For this column, I want to focus in particular on recent developments with the Medicare Incentive Payment System (MIPS), created under the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (MACRA).

Beginning in 2019, MIPS accelerates the move to value-based instead of volume-based purchasing by making adjustments to physician payments based on four criteria—quality, resource use (cost), clinical practice improvement activities, and meaningful use of electronic health records (EHRs). The MIPS criteria will subsume and replace several current quality reporting initiatives, including the Physician Quality Reporting System, the Value-Based Payment Modifiers for physician payments, and the Medicare Incentive Program for Meaningful Use of Certified EHR Technology (Meaningful Use).

Although 2019 may seem a long way away for some of us, the MIPS train is already moving out of the station. In December 2015, in response to a MACRA mandate, the Centers for Medicare & Medicaid Services (CMS) released a draft Quality Measure Development Plan (MDP) for application under MIPS and also for application to certain Medicare alternative payment models (APMs).[1] According to CMS, the final MDP, taking into account public comments,[2] will be posted on the CMS.gov website by May 1, 2016, followed by updates annually or as otherwise appropriate. The MDP will serve as a strategic framework for the future of clinician quality measure development to support MIPS and APMs.

Acting CMS Administrator Andy Slavitt, in comments at the J.P. Morgan Annual Health Care Conference in January 2016, elaborated on how MACRA and MIPS will subsume and replace one of the current quality reporting initiatives, the Meaningful Use Program.[3] Slavitt indicated that the focus of EHR metrics will move away from rewarding providers for the use of technology and toward the outcome they achieve with their patients. He also indicated that providers will be able to customize their goals so that tech companies can build around the individual practice needs, not the needs of the government. In order to promote this result and "level the technology playing field," as well as avoid data lock, Slavitt indicated that CMS will require open application programming interfaces. Slavitt also emphasized that CMS is "deadly serious" about interoperability.

Finally, as a prelude to evaluating physicians in another of MACRA's four core areas, i.e., resource use, CMS has been using certain "episode groups" it created under the Affordable Care Act to give physician groups feedback about their resource use.[4] CMS is specifically seeking stakeholder input on the future role of episode groups in resource use measurement under MIPS.[5]

In sum, though we still have almost three years until the onset of MIPS, there are already a lot of implementation steps occurring for MIPS. We at the RAP PG look forward to keeping you informed of future developments in these very fluid and interesting reimbursement times.

Sincerely,

Claire

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1 *See* www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Draft-CMS-Quality-Measure-Development-Plan-MDP.pdf, last accessed January 24, 2016.

2 CMS has invited public comments until March 1, 2016.

3 *See* http://blog.cms.gov/2016/01/12/comments-of-cms-acting-administrator-andy-slavitt-at-the-j-p-morgan-annual-health-care-conference-jan-11-2016/, last accessed January 24, 2016.

4 *See* www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html, last accessed January 24, 2016.

5 CMS has solicited these comments until February 15, 2016. *See* www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-groups-summary.pdf, last accessed January 24, 2016. CMS also issued a Request for Information in October 2015 entitled "Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models," the comment period for which closed November 17, 2015. *See* https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-26568.pdf, last accessed January 24, 2016.

The First Mandatory Manifestation of the Specter of Alternative Payment Models: CMS Comprehensive Care for Joint Replacement Model

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On November 12, 2015, the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare & Medicaid Services (CMS) made the most significant move so far toward their stated goal to transition 50% of traditional Medicare fee-for-service reimbursement to alternative payment models by 2018 by issuing the final rule for a mandatory bundled payment based program for some of the nation's most common surgical procedures (Final Rule).[1] The program has been titled the Comprehensive Care for Joint Replacement model (CJR) and, as the title suggests, focuses on total hip and total knee replacement procedures, termed in CJR as "lower extremity joint replacement episodes" (LEJR Episodes).

CJR will be in effect for five calendar years from April 1, 2016 to December 31, 2020, including five performance periods ending December 31 of each year. Hospitals will be held accountable and potentially rewarded for the cost and quality of LEJR Episodes, with actual performance compared to target prices during a retrospective bundled payment process. Each LEJR Episode includes the acute care hospital stay and a significant portion of recovery, ending 90 days following discharge. Participation in CJR will be mandatory for most hospitals in 67 metropolitan statistical areas (MSAs), down from 75 in the CJR proposed rule, and those hospitals will be held accountable for the financial performance and quality of care provided not only during the inpatient hospital stay but also during the variety of interactions with patients during their recovery.[2] Potential rewards for lowering cost and increasing quality will be available during the first performance period, while potential penalties will not kick in until 2017.

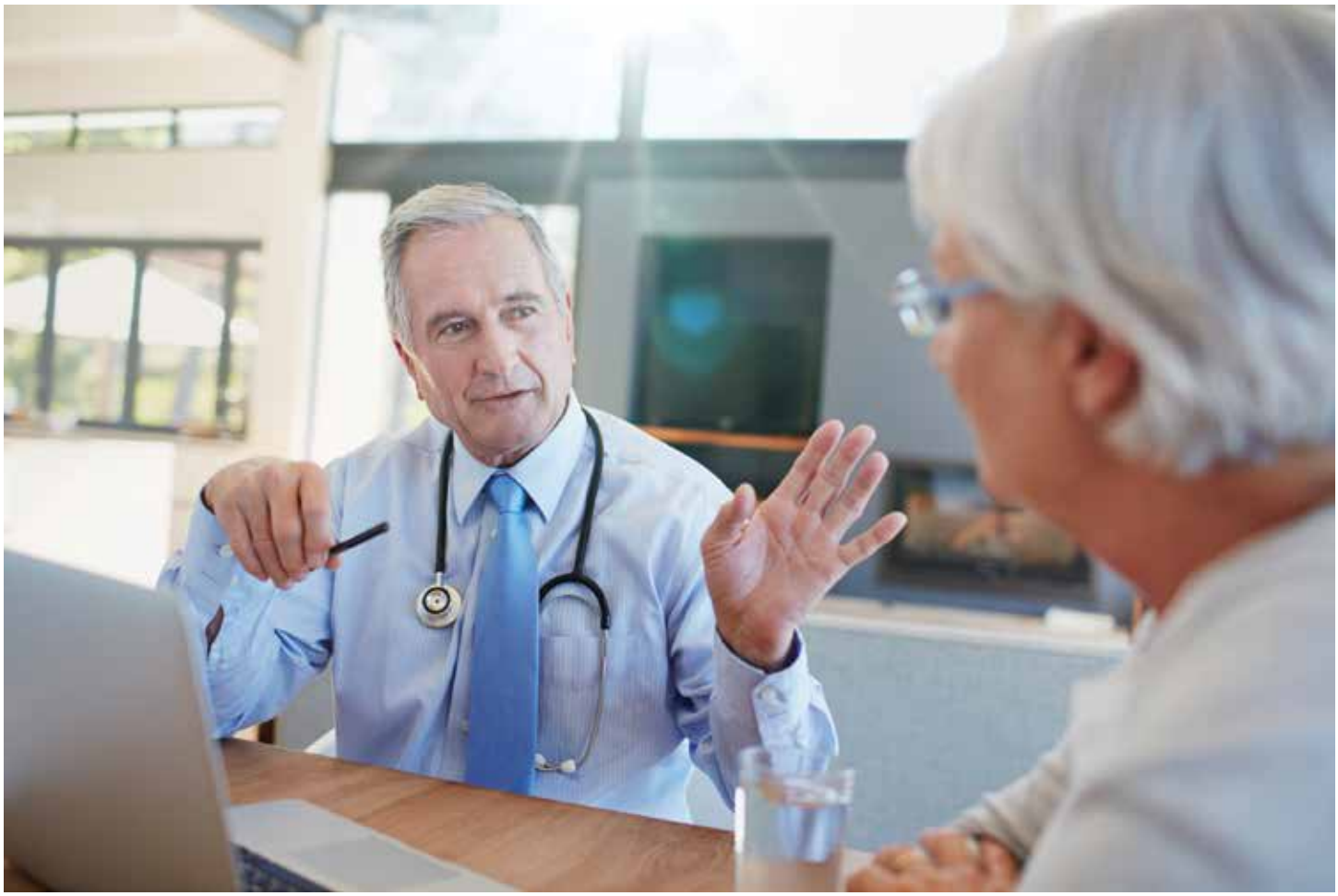
Even if your region was not chosen for CJR, bundled payments and other alternative payment models are the specter haunting health care, and every organization would benefit from beginning to prepare for more widespread implementations of these payment models. While CMS gave some warning, the rapid shift away from traditional fee-for-service reimbursement and ambitious implementation schedule of CJR has caught many health care organizations by surprise. As noted in a previous *RAP Sheet* article, the foundation necessary to be successful under these new payment models for participating providers, especially hospitals, includes: (1) the ability to offer services and align with providers across the continuum of care; (2) the ability to measure and monitor outcomes through the use of sophisticated data gathering and financial analysis, including the use of an electronic medical record; (3) strong executive and medical leadership; and (4) active and meaningful engagement of physicians and key stakeholders.[3] This article will provide a high-level summary of some core elements of CJR, including what can be learned from participation in prior CMS programs, and will discuss steps that hospitals and other stakeholders can take in preparation for participation in CJR. Additional information and periodic updates regarding the program are available at the CMS Innovation Center website for CJR.[4]

Why Hospitals? Why Now?

The Final Rule concluded the rulemaking process triggered by the release of a proposed rule in July 2015 (Proposed Rule),[5] which was followed by more than 400 public comments. While CMS noticeably dropped a "C" from the original "CCJR" acronym, it did not reduce or delay substantially the obligations that hospitals will have in the program. With the exception of a token delay to April 1, 2016,[6] for the initiation date of CJR, a more gradually phased in downside risk of loss for hospitals, material changes to quality metrics, and other more insubstantial revisions, the Final Rule concentrates largely on providing further rationale and context for the model established by the Proposed Rule.

Many prominent national associations made their full comments to the Proposed Rule public, and certain themes were common. Nearly all public comments proposed significant delays and criticized the lack of time for preparation and current lack of infrastructure of many potential participant hospitals.[7] CMS has now reiterated in many locations in the Proposed Rule and Final Rule that the stated goal of the program is to evaluate the impact of bundled payments across a broad spectrum of hospitals with varying levels of infrastructure and experience in entering into risk-based reimbursement arrangements, acknowledging that this variation will be part of the CJR evaluation process.[8] The lack of access, until 60 days into 2016, to claims data for the baseline years used for calculating the target price, was a significant impetus for delaying the initiation of CJR until April 1, 2016, given that CMS has admitted such data will be integral to participant hospitals' ability to monitor trends, identify cost drivers, and pinpoint areas where care practice changes are appropriate.[9]

Part of the rationale for making CJR mandatory for so many MSAs is to greatly expand the scope of providers by which CMS can measure and weigh the efficacy of bundled payment programs, and to avoid the selection bias that is inherent to voluntary programs like the Bundled Payments for Care Improvements (BPCI) Initiative.[10] By August 2015,



a total of 360 Awardees and 1,755 associate providers had entered into Phase II (the risk-bearing stage) of a BPCI model initiative.[11] In a review of the results of Model 2 released in 2015, it was found that all hospital participants in the program had more than 100 beds and significantly higher occupancy rates than average Medicare participating hospitals.[12] It is clear that CMS, in designing CJR, desired to capture a more representative cross-section of Medicare providers in the program and at the same time dramatically increase participation in bundled payment type reimbursement programs. CJR will require participation of an estimated 800 hospitals encompassing about 111,000 annual procedures (one quarter of the total procedures in this category in Medicare), which will more than double current participation in BPCI when all associated providers are accounted for.

Hospitals participating in other voluntary Medicare programs, such as the Medicare Shared Savings Program (MSSP), are encouraged to continue their participation in such programs but will be required to participate in CJR as well.[13] However, certain hospitals are excluded from participating in CJR, including hospitals participating in Model 1 or Phase II of Models 2 or 4 of the BPCI initiative for LEJR Episodes. Further, certain MSAs were excluded from the original selection process where participation in BPCI initiatives was high, and removed from the Final Rule for the same reason, to reduce overlap with those programs and increase the scope of hospitals on which CMS could test the CJR payment model. Through various reconciliation processes, spending reductions will be attributed to the correct CMS model or program, with a basic hierarchy of applicability of savings flowing first to BPCI initiatives, then to Accountable Care Organization (ACO) models such as MSSP, and finally to CJR.[14] Where LEJR Episodes that would otherwise qualify for CJR are based on a procedure performed by a surgeon participating as an episode initiator in BPCI, CMS will simply "cancel or never initiate" the CJR episode.[15] The method by which determinations will be made as to allocation of savings interfacing with MSSP is complex, and raises the need for each hospital to develop a high level of specialization (or to hire an entity that has such specialization) in the calculation processes of reconciliation to ensure that mistakes are not made by CMS. CMS further admits that due to issues that will likely only arise through the first reconciliation process, they will revisit the approach to overlap with MSSP in later rulemaking.[16]

Who will be Affected?

Participation in CJR will be required for most hospitals with a physical presence in any one of 67 MSAs,[17] defined as counties associated with a core urban area that has a population of at least 50,000.[18] Selection methodology was random and structured to ensure that the participants in CJR would be representative of hospitals that perform a variety of volumes of LEJR procedures at a variety of current costs to CMS.[19]

Because participation in CJR will be mandatory for most hospitals paid under the Inpatient Prospective Payment System (IPPS) who are physically located in the selected MSAs, there will be no application process or other similar screening of participant hospitals or other providers.

CMS expects hospitals to spread both the risks and possible incentives inherent to the model with other providers in the LEJR Episode and argues that hospitals, as opposed to ACOs or physician group practices (PGPs), are in fact in the best position to facilitate such arrangements.[20] Other Medicare-enrolled providers, including physicians, long term care hospitals, skilled nursing facilities, home health agencies, and ambulance services (Collaborators), are expected to participate in CJR through various arrangements with the hospital serving as the central hub with oversight over the continuum of care provided to LEJR patients. In order to reduce the necessity for changes to core billing and payment processes, all providers in CJR will continue to receive traditional fee-for-service payments throughout the life of CJR. This may serve as a roadblock to partnering with many Collaborators, but CMS apparently expects the possibility of sharing in incentive payments to motivate participation in the program, even absent any mandatory share in the potential for downside risk.

While some previous programs, including those related to quality, have imposed financial penalties for poor performance, this is the first Medicare program involving bundled payment based reform to be made mandatory for providers in a region. CMS stated in the Proposed Rule that much can be learned from previous voluntary reimbursement reform programs, including the MSSP and the Oncology Payment Model, but it is the BPCI model program that served as the inspiration for much of the CJR infrastructure.[21] Total hip and total knee replacement procedures are some of the most frequently performed surgical procedures in the country, with relatively consistent clinical approaches and a high level of homogeneity between implants, with significant regional variation in expenditures and intensity of post-acute care provision. This type of procedure, which arguably lends itself to "best practices," but which still suffers from a large amount of variation in cost, made it the proverbial low-hanging fruit for CMS to test this type of payment structure.

Scope of the Episode

An LEJR Episode will start upon admission of a Medicare beneficiary to a participating hospital discharged under Diagnosis Related Group (DRG) 469 or 470, and will end 90 days after discharge of that individual from the participant hospital.[22] The 90-day period was selected in order to capture the full transition of care following an LEJR procedure, and CMS noted that 86% of BPCI Model 2 participants also chose the 90-day post-discharge episode definition.[23]

The episode will include all related services paid under Medicare Part A and Medicare Part B, with certain limited exclusions primarily relating to existing chronic conditions.[24] For clarity, this includes, but is not limited to, the following categories of items and services: physician's services; inpatient hospital services; long term care hospital services; inpatient rehabilitation facility services; skilled nursing facility services; home health agency services; hospital outpatient services; durable medical equipment; and Part B drugs. As indicated by this structure, it is the intent of CMS to make the hospital accountable for both the cost and quality of care across the entire continuum of care provided to an individual in an LEJR Episode, not merely the portion for which it has historically been responsible.

CMS has stated that on average the IPPS payments constitute 50% of the total payments for an LEJR Episode, with the post-acute portion constituting the largest percentage of the remaining half.[25] It follows that hospitals will likely find the majority of cost savings opportunities in reducing IPPS costs and increasing the efficiency of post-acute care services.

Interestingly, CMS has excluded any new technology add-on payments for drugs, technologies, and services from the LEJR Episode, under the argument that they did not desire to hamper beneficiaries' access to new technologies or to burden hospitals that choose to use such products.[26] From the perspective of implementation, this policy decision may have a significant impact on the ability of hospitals to work cooperatively with surgeons to consolidate implant options or to standardize clinical processes, which is often the first step taken in an attempt to reduce contract prices for these implants.

Payment and Calculation of Episode Target Prices

All providers and suppliers who care for Medicare beneficiaries during the course of an LEJR Episode will continue to bill and be paid under traditional Medicare fee-for-service systems. Following each CJR year, all Medicare claims made for services to beneficiaries in an LEJR Episode will be aggregated at the episode level and compared to target prices set for each hospital by CMS. Where the actual episode payments are below the target price, Medicare will be responsible for a payment of that amount back to the hospital (Reconciliation Payment) as long as certain quality metrics are met, and where actual episode payments are

above the target price, the hospital will be responsible for repayment of those amounts to Medicare (Medicare Repayments) in years two through five of CJR. Responsibility for Medicare Repayments will be phased in, with the total possible Medicare Repayment obligations capped at 5% of the target price multiplied by the number of LEJR Episodes initiated at the hospital during year two, and increasing to 10% in year three, and finally to 20% in years four and five.[27] Similarly, to protect CMS interests, Reconciliation Payments will be capped at the same percentages.

The target price will be set by CMS annually for each hospital, will be set separately for each DRG, and will by default include a 3% discount on all claims made during an LEJR Episode (up from 2% in the Proposed Rule), but this discount percentage will be impacted by performance in relation to quality metrics. CMS recognized the need for at least some basic risk stratification within these DRGs in response to extensive comments that there was no defined risk-adjustment process for more vulnerable or predictably higher-cost patients.[28] Noting the significantly higher spending associated with more complex cases involving hip fracture, CMS decided to set separate target prices for these cases within each DRG.[29]

This means hospitals will have to drive LEJR Episode costs down 3% to merely break even in later years of CJR if they perform poorly in relation to quality metrics. Target prices will be based on a three-year period, beginning with January 1, 2012 and moving up by one year beginning in year three of CJR. Significantly, the target price will blend historical performance of the hospital on LEJR Episodes with regional performance in the U.S. Census Division for the participant hospital, which constitutes a significantly larger geographic region than the MSAs in which participation will be based.[30] In future years the portion of the target price based on regional spending will increase, until in years four and five the target price will be based entirely on regional spending performance. CMS hopes that by transitioning to regional pricing as the basis for target prices in later years of CJR, hospitals will have sufficient experience in Care Redesign to have addressed what CMS refers to as "unnecessary hospital-specific variation in episode spending."[31]

To further address the potential for outlier cases which would significantly affect hospital financial obligations, CMS will exclude certain high-payment episodes that fall two standard deviations above the average LEJR Episode price for the region.[32] While it seems that CMS understands that each hospital's case mix in relation to beneficiaries' general health status and demographics will impact total costs in CJR episodes, they were at best hesitant to build a payment infrastructure that recognizes this type of inherent variation between hospitals in a region, and are at worst alleging that variation in costs due to these factors is without merit.

Ancillary (but Important) Issues

Quality Metrics

In the Final Rule, CMS revised the approach to quality metrics from a threshold methodology to a composite score for both current performance and improvement in comparison to past performance, but maintained the approach of defining four performance categories tied to varying discount percentages. The discount percentage also will vary according to whether a Reconciliation Payment is earned, or a repayment is required, so that hospitals that perform well in relation to quality measures will be rewarded by significant reductions to the discount percent (for instance, 0.5% in year two for the highest performers should they owe a repayment).[33]

The Final Rule removed the proposed readmission rate metric, and the remaining quality metrics include:

- Hospital Level Risk Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty; and
- Hospital Consumer Assessment of Healthcare Providers and Systems Survey.

Hospitals will earn additional points toward their composite score if they successfully submit voluntary patient-reported functional outcome data and certain risk variable data.[34]

Waivers of Certain Medicare Program Requirements

CMS granted certain limited program waivers to provide some additional flexibility in provision of services to beneficiaries in CJR. Those waivers include:

- Waiver of the skilled nursing facility three-day rule for coverage of skilled nursing facility services following the anchor hospitalization for an LEJR procedure;
- Waiver of the "incident to" rule for physician services provided during the course of a home visit, by permitting certain licensed clinical staff of a physician to furnish services during a home visit;
- Waiver of the geographic site requirement and the originating site requirement for telehealth services to permit telehealth visits to originate in the beneficiary's home;[35] and
- Waiver of the limitation on certain beneficiary incentives provided by the participant hospital.[36]

CMS declined to issue a waiver related to discharge planning requirements, and instead reiterated the need for providers to honor beneficiary choice so that "recommendations [for discharge] are based on clinical needs and not inappropriate cost savings."[37] CMS appears to be concerned that since beneficiaries may not opt out of participation in CJR, certain protections must be maintained to prevent limitation of a beneficiary's ability to choose among numerous Medicare

providers following discharge from the hospital. The lack of flexibility in this area of discharge planning may be an additional roadblock to hospital success in CJR, especially where certain post-acute care providers may be hesitant to enter into a contractual relationship with the hospital and are known high-cost providers.

How to Spread the Wealth… and Risk?

In CJR, only hospitals will be direct risk-bearing entities, eligible to receive Reconciliation Payments and directly held liable for any Medicare Repayments. Still, CMS understands the need, and has provided the infrastructure necessary, to align the financial incentives of various Collaborators. Participant hospitals will be permitted and expected to enter into agreements with Collaborators (Collaborator Agreements), which involve arrangements to allocate financial incentives (Sharing Arrangements). Collaborators and PGPs that directly furnish services to CJR beneficiaries will be permitted to share in Reconciliation Payments and any internal cost savings attributable specifically to Care Redesign efforts (Gainsharing Payments), and share in accountability for Medicare Repayments.[38]

Generation of internal cost savings will depend on the hospital's ability to reduce the "cost" to providers of providing services associated with LEJR Episodes. Considering recent studies indicate the range of average implant costs per case vary from $1,797 to $10,155 for total knee replacement procedures, and from $2,392 to $12,651 for total hip replacement procedures,[39] it is likely that hospitals will discover significant returns in exchange for devoting additional resources to driving down implant acquisition costs. This can most often be accomplished through standardization of implant options and establishment of clinical best practices based on evidence-based approaches.

Among many other elements, Collaborator Agreements will be required to obligate Collaborators to participate in Care Redesign efforts, and like BPCI, will be required to contain a full description of the methodology and accounting formula for calculating any Gainsharing Payments.[40] In stark contrast to BPCI Model 2, CJR "conveners" who do not provide actual care to beneficiaries, but instead coordinate and provide administrative services in support of a program, will not be allowed to receive a portion of Reconciliation Payments and instead will be limited to fair market value payments commensurate with the services they provide.[41] Similar limitations are in place related to any entity that does not actually provide health care services to a beneficiary in CJR, including ACOs, which may provide data analysis or care coordination services on behalf of a hospital.[42] Participant hospitals may share up to 50% of the total downside risk in relation to possible Medicare Repayments, but will have to use the possibility of Gainsharing Payments as incentive to convince Collaborators to share in this risk. Among other limitations, CMS has set forth very specific content for both Sharing Arrangements and Collaborator Agreements.[43]

As expected given past experiences with BPCI, waivers of certain fraud and abuse laws (including the physician self-referral prohibition[44] and the federal Anti-Kickback Statute[45]) were released jointly by CMS and the HHS Office of Inspector General in conjunction with the Final Rule.[46] The waivers relate only to certain flows of funds in CJR, and are limited to Gainsharing Payments made by hospitals to various Collaborators and distributions of Gainsharing Payments made by PGPs to member physicians, along with certain patient engagement incentives that will be permitted to be made to beneficiaries in CJR. The waivers do not relate to the civil monetary penalty (CMP) law,[47] as OIG opined that due to the fact that payments to reduce medically unnecessary care are no longer prohibited, no waiver of the gainsharing CMP is needed.[48]

Still, compliance with the granular requirements for Collaborator Agreements will be considered as a prerequisite for application of the waivers, and they are not as broad as those instituted in the MSSP. As noted previously, any arrangements with entities that do not provide care to beneficiaries in an LEJR Episode, who may not receive Gainsharing Payments, must comply with all fraud and abuse laws or fit within an existing exception or safe harbor. The same holds true for any arrangements with Collaborators for purchase of services or supplies. In order for Collaborators to receive any Gainsharing Payments, and for those payments to be covered by the waivers, a Participation Agreement must have been executed prior to the provision of any care for which the Gainsharing Payment is associated.[49]

The need for specific waivers to various fraud and abuse laws continues to be a barrier to more widespread provider alignment and payment reform. CMS has recognized this discontinuity, commenting that, "The physician self-referral law, by design, separates entities furnishing DHS from the physicians who refer Medicare patients to them. Evolving health care delivery and payment models, within both the Medicare and Medicaid programs and programs sponsored by non-federal payors, are premised on the close integration of a variety of different health care providers…"[50] The narrowness of the waivers granted for CJR is surprising given the tension between mandatory participation of hundreds of hospitals, and the significant risk of fraud and abuse violations inherent to developing the types of relationships with providers, and other entities specializing in population health services, which would likely be required to accomplish the goals CMS has set forth for the program. CMS has certainly succeeded in ensuring that CJR will effectively test the ability of hospitals alone to succeed in a retrospective bundled payment model. But, in successfully isolating the hospital from the perspective of financial accountability, CMS may have hampered the more efficient

spread of cost savings and best practices by preventing gainsharing with entities that have experience with BPCI and other bundled payment models. Not all hospitals have the resources to develop their own specialized skillset necessary to succeed in a bundled payment system.

Conclusion

Hospitals in the 67 selected MSAs are no longer facing a mere specter of value-based reimbursement programs, but instead are facing a very real deadline of April 1, 2016 for implementation of payment reforms. Even though down-side risk will not take effect until 2017, experience with BPCI Model 2 has revealed that implementation typically takes between six months and a year, suggesting that all hospitals in the 67 MSAs should already have requested the available baseline data, and should be currently working on their implementation plans and Care Redesign. Further, as noted above, if hospitals wish to use any Gainsharing Payments generated this first performance year as incentives for providers to collaborate further in future years, they *must* enter into Collaborator Agreements as soon as possible.

An effective preparation process for the hospitals involved in CJR should include the following:

- Evaluate hospital resources in the areas of data analytics, supply chain contracting, care coordination, evidence-based medicine, and physician engagement and reallocation or devotion of additional funds to these resource categories as necessary.
- Engage physicians and other Collaborators early in the process to begin to generate the trust and cooperative environment that will be necessary for success in CJR.
- Develop relationships with numerous other Collaborators, including home health agencies and long term care facilities, with whom most hospitals have never previously had contractual relationships.
- Establish the necessary elements of Care Redesign that will be required to accomplish the required quality metrics and cost savings under CJR.
- Work with internal or outside legal counsel to draft template Collaborator Agreements with various categories of Collaborators.
- Develop internal specialists in the CJR reconciliation and payment process in case of CMS errors in calculations.

Current participants in MSSP and hospitals with robust population health infrastructures will undoubtedly have

certain advantages as they face participation in CJR. Still, hospitals and other providers can learn from the previous guidance issued by CMS in relation to bundled payment programs like BPCI Model 2, and the experiences of those prior participants. The template BPCI Model 2 Awardee Agreement can serve as the basis for many necessary terms and requirements of Sharing Arrangements and Collaborator Agreements. Further, Attachment B to the template BPCI Model 2 Awardee Agreement can serve as the basis for a readiness assessment for CJR participant hospitals, and even a model for what should be contained in any Care Redesign effort required by CJR.

Regardless of a hospital's presence in the selected MSAs, their current financial status, or success in other voluntary payment models, any organization that intends to prosper in future years would be well served to begin the process of preparing for value-based payment models by noting results of CJR and examining successful examples of CJR participants, as CJR is just the first manifestation of the very real specter of Medicare payment reform.

1 80 Fed. Reg. 73274, 73274 – 73554 (Nov. 24, 2015) (implementing 42 C.F.R. Part 510).
2 *See generally* https://innovation.cms.gov/Files/fact-sheet/cjr-providerfs-finalrule.pdf for a general fact sheet published by CMS related to the CJR program on November 16, 2015.
3 *See* Skeels, Jennifer F. and Katie J. Miller, *Understanding Health Care Quality Payment Methodologies: The First Step to Thriving in a Value-Based Reimbursement World*, The RAP Sheet: A Publication of the American Health Lawyers Association Regulation, Accreditation, and Payment Practice Group (Vol. 18, Iss. 2, June 2015), p. 6.
4 https://innovation.cms.gov/initiatives/cjr.
5 *See* 80 Fed. Reg. 41198, 41198-41315 (July 14, 2015), as corrected by 80 Fed. Reg. 51504, 51504-51506 (Aug. 25, 2015).
6 *See* 80 Fed. Reg. at 73327 (discussing 42 C.F.R. § 510.200(a)).
7 *See, for example,* American Hospital Association, "RE: CMS-5516-P, Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Joint Replacement Services; Proposed Rule (Vol. 80, No. 134), July 14, 2015" (Sept. 8, 2015), *available at* www.aha.org/advocacy-issues/letter/2015/150908-cl-cms-5516p.pdf, and Association of American Medical Colleges, "Re: Comprehensive Care for Joint Replacement Model Proposed Rule, File Code CMS-5516-P" (September 4, 2015), *available at* www.aamc.org/download/442290/data/aamccommentsontheccjrproposedrule.pdf.
8 *See* 80 Fed. Reg. 41198, 41206 (July 14, 2015) and 80 Fed. Reg. at 73278.
9 *See* 80 Fed. Reg. 41198, 41292 (July 14, 2015).
10 *See* 80 Fed. Reg. at 73278.
11 *See* "CMS announces additional participants in pilot project to improve care and reduce costs for Medicare," *available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-08-13.html.
12 *See* The Lewin Group, *CMS Bundled Payments for Care Improvement (BPCI) Initiative Models 2-4: Year 1 Evaluation & Monitoring Report*, (Feb. 2015), p. 4, *available at* http://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf.
13 *See* 80 Fed. Reg. at 73281.
14 *See* 80 Fed. Reg. at 73391-73398 (discussing 42 C.F.R. § 510.305).
15 *See id*. at 73390.
16 *See id*. at 73397.
17 *See id*. at 73288.
18 *See* https://innovation.cms.gov/initiatives/cjr for a list of selected MSAs.
19 *See* 80 Fed. Reg. at 73294.
20 *See id*. at 73280.
21 *See generally* http://innovation.cms.gov/initiatives/bundled-payments/ for information regarding the four BPCI models.
22 *See* 80 Fed. Reg. at 73324 (discussing 42 C.F.R. § 510.210).
23 *See id*. at 73321.
24 *See id*. at 73313-73315, and *see* https://innovation.cms.gov/Files/worksheets/ccjr-exclusions.xlsx for a full list of all exclusions.
25 *See* 80 Fed. Reg. at 41205.
26 *See* 80 Fed. Reg. at 73308.
27 Note that these caps apply generally, but the cap for Medicare Repayment obligations for rural, sole community, Medicare dependent, and rural referral center hospitals will be set even lower at 3% for year two and 5% for years three through five of CJR. *See* 80 Fed. Reg. at 73406 (discussing 42 C.F.R. § 510.305(e)(1)(v)(D)).
28 *See* American Hospital Association, "RE: CMS-5516-P, Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Joint Replacement Services; Proposed Rule (Vol. 80, No. 134), July 14, 2015" (Sept. 8, 2015), *available at* www.aha.org/advocacy-issues/letter/2015/150908-cl-cms-5516p.pdf.
29 *See* 80 Fed. Reg. at 73340 (discussing 42 C.F.R. § 510.300(a)), and *see also* the list of ICD-10 codes that will cause an episode to qualify for involvement of a hip fracture at https://innovation.cms.gov/Files/worksheets/cjr-icd10hipfracturecodes.xlsx.
30 *See id*. at 73349.
31 *See id*. at 73347.
32 *See* 80 Fed. Reg. at 73382, and *see* https://innovation.cms.gov/Files/worksheets/ccjr-avgreghistepisodes.xlsx for a table of average historical episode costs by region and ceiling prices for use in calculating target prices and aggregating hospital performance on cost.
33 *See* 80 Fed. Reg. at 73381 (discussing 42 C.F.R. § 510.315).
34 *See id*. at 73364.
35 *See id*. at 73450.
36 *See id*. at 73437-73461 (discussing 42 C.F.R. § 510.600, 605, 610, 615, and 620).
37 *See id*. at 73516.
38 42 C.F.R. § 510.2.
39 Robinson, James C. et. al, *Variability in Costs Associated with Total Hip and Knee Replacement Implants*, The Journal of Bone and Joint Surgery (2012 Sep 19; 94 (18)), p. 1693 – 1698.
40 *See* 80 Fed. Reg. at 73429.
41 *See id*. at 73285.
42 *See id*. at 73286.
43 *See id*. at 73429-73433 (discussing 42 C.F.R. § 510.500).
44 Section 1877 of the Social Security Act.
45 Section 1128B(b)(1)-(2) of the Social Security Act.
46 *See* "Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model" (November 16, 2015), *available at* www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf.
47 Sections 1128A(a)(5), (b)(1), and (b)(2) of the Social Security Act.
48 *See* "Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model" (November 16, 2015), p. 2, *available at* www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf.
49 *See* 80 Fed. Reg. at 73428-73429.
50 *See* 80 Fed. Reg. at 41928.

Noteworthy DAB/CRD Provider Enrollment Decisions from the Third and Fourth Quarters of 2015

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The U.S. Department of Health and Human Services (HHS) Departmental Appeals Board (DAB) and Civil Remedies Division (CRD) provide impartial, independent review of disputed decisions in a wide range of programs, including Medicare enrollment. The outcomes in DAB and CRD cases related to Medicare enrollment provide health care lawyers with a better understanding of Medicare enrollment rules and current regulatory enforcement trends. Understanding the decisions and the rules can be the difference between a provider's proper enrollment in Medicare with timely billing privileges and the disenrollment of a provider for a seemingly small, administrative error, such as failing to update practice location information. This article examines some of the noteworthy DAB and CRD provider enrollment decisions from the third and fourth quarters of 2015.[1]

Responsibility of Provider/Supplier to Provide Complete Application Despite Issues in Communication with MAC or Inaccurate Guidance from MAC Representatives

A November CRD decision demonstrates that the onus for ensuring that an application is completed and that the Medicare Administrative Contractor (MAC) has the information it needs to process the application falls on the provider or supplier—even if the provider or supplier is unable to access the MAC's communications with the provider or supplier.[2] In Decision No. CR4412, the MAC sent an email to the Petitioner, attaching a letter dated October 8, 2014, that outlined the deficiencies of an enrollment application the Petitioner had submitted; the MAC did not also send a hard copy of the letter via regular mail. The MAC sent the email to Ms. Vavas, an employee of the Petitioner responsible for the Petitioner's Medicare application. Vavas did not receive the email attachment but instead received a series of blank emails from the MAC. She called the MAC more than once, but the MAC's representatives told her they were unable to provide any explanation of the blank emails. As a result, the Petitioner did not supply the MAC with the requested information within 30 days. On December 15, 2014, Vavas received an email from the MAC with an attached letter—which she was able to open and read—denying the enrollment application.

Although the Petitioner argued that the MAC "ineffectively communicated" with Vavas, the Administrative Law Judge (ALJ) found that there was no reviewable error committed by the MAC. The MAC identified the deficiencies, notified the Petitioner of such deficiencies, and gave the Petitioner the opportunity to cure them. The ALJ also found that had the Petitioner filed a complete application initially, it would not have encountered any problems. Finally, the ALJ found that there was no willful wrongdoing by the MAC: The contractor sent its notice to the correct address but Vavas did not receive it.

Similarly, in another November CRD decision, Decision No. CR4400, an ALJ ruled that even though a MAC representative erroneously advised a Petitioner to withdraw and resubmit its enrollment application, the effective date of enrollment was still tied to the application that was processed to completion,[3] not the application submitted earlier but withdrawn upon the advice of a MAC representative.[4] In that case, the Petitioner filed a Medicare enrollment application that was missing information and contained several inaccurate statements, including the Petitioner's practice location, telephone number, and fax number. The Petitioner voluntarily withdrew its first application because a MAC representative told the Petitioner that the errors and omissions in the first application necessitated resubmission of the application, as opposed to amendment of the first one. The Petitioner filed a new application on February 23, 2015, which the MAC subsequently approved. The MAC assigned an effective date of participation of February 23, 2015.

The Petitioner argued there was "affirmative misconduct" on the part of the Centers for Medicare & Medicaid Services (CMS) because of the MAC representative's mistaken guidance. However, the ALJ rejected the argument as neither the ALJ nor the DAB is authorized to provide equitable relief by reimbursing or enrolling a supplier who does not meet statutory or regulatory requirements.[5] Additionally, even if the representative had provided misleading information, the Petitioner offered nothing to show a deliberate provision of false information to the Petitioner that would amount to "affirmative misconduct."

Revocation of Billing Privileges and Enrollment after Certification of False or Misleading Statements

A July CRD decision underlined the importance of providers and suppliers taking seriously the certification of an enrollment or change of information application provided to Medicare. Providers and suppliers must carefully review each application before submission to Medicare, even if the application is prepared by an employee or independent contractor since, ultimately, the provider or supplier signing the certification is responsible for the accuracy of the application's contents. CMS may revoke a provider or supplier's enrollment and billing privileges if the supplier "certified as 'true' misleading or false information on the [Medicare] enrollment application."[6]

In Decision No. CR 4209, CMS notified the Petitioner, a nurse anesthetist in Michigan, by letter that it was revoking

her Medicare enrollment and billing privileges because the Petitioner failed to disclose two certified registered nurse anesthetist license suspensions and one license revocation in Medicare enrollment applications she submitted in 2011 and 2013.[7] CMS presented evidence demonstrating that the Petitioner submitted two separate Medicare enrollment applications that contained false or misleading information—that no adverse actions had been taken against her when, in fact, three adverse actions had been taken. Despite the Petitioner's argument that she was unaware that the applications were erroneous because she did not prepare or submit them, the ALJ affirmed CMS' decision to revoke the Petitioner's Medicare enrollment because she had certified applications that contained false or misleading statements.

Revocation of Billing Privileges and Enrollment for Failure to Report Change of Address

A number of decisions from the third and fourth quarters of 2015 demonstrate the importance of providers and suppliers keeping their enrollment information up-to-date, particularly regarding their practice locations.[8] In a November CRD decision, Decision No. CR4321, an ALJ upheld revocation of a supplier's enrollment and billing privileges because the supplier failed to timely and properly notify the MAC of a change in location.[9] This decision emphasized the importance of providing proper notice, using the correct form and filling in the form correctly. Here, the Petitioner completed a revalidation and, as part of the revalidation, in Section 4 (Practice Location Information), the Petitioner checked the "add" box and listed 16975 Farming Road, Livonia, Michigan as a new practice location. The Petitioner submitted a CMS-855I form to the MAC dated February 1, 2014, in which the Petitioner did not make a selection in Section 1A (reason for application) and in Section 2B placed an "x" in the box indicating that the form was related to "Practice Location Information, Payment, Address and Medical Record Storage Information." In Section 4, the Petitioner placed an "x" next to "add," entered an effective date of February 1, 2014, and entered 4700 Greenfield Road, Dearborn, Michigan. The Petitioner did not check the "change" or "delete" boxes in Section 4. CMS inspectors subsequently attempted to conduct site verification at the Petitioner's 16975 Farmington Road practice. The MAC notified the Petitioner by letter dated December 1, 2014, that his billing privileges would be revoked because he had failed to notify CMS within 30 days of a change of practice location.

Despite conceding that he failed to report the change in practice location, the Petitioner argues that he indirectly notified CMS that the location at issue was closed because he omitted that location from the CMS-855I form he submitted dated February 1, 2014. The ALJ rejected the Petitioner's argument that CMS should have inferred a closure of location based on the second CMS-855I form as the regulations impose an affirmative duty on participants to report a change in practice location. Thus, the ALJ found the Petitioner's failure to report within 30 days the closure of one of his practice locations to be a sufficient basis for CMS to revoke the Petitioner's enrollment and billing privileges.

Similarly, an October CRD decision, Decision No. CR4321, demonstrated that notification to a state agency of a change in address was not the same as notifying Medicare or a MAC, again emphasizing the importance of providing notice exactly as required by Medicare.[10] After receiving a letter from the MAC that its billing privileges were revoked because the MAC had determined that the Petitioner, a home health agency, was no longer operational, the Petitioner explained that it had notified the Texas Department of Aging and Disability Services, the state agency, 30 days in advance of its relocation, but had not submitted a CMS-855A to the MAC. The ALJ upheld the revocation of billing privileges because the Petitioner had not notified Medicare of the location change.

Likewise, in an October CRD decision, the Petitioner, a home health agency, attempted to use a letter to the MAC to provide notice of a location change rather than one of Medicare's forms (either filing an 855 Form or using the Provider Enrollment Chain and Ownership System (PECOS)).[11] In Decision No. CR4369, the ALJ noted that a provider or a supplier participating in Medicare must comply with the program's participation criteria. Medicare's Program Integrity Manual Section 15.1.3 provides two ways—and only these two ways—for a provider or supplier to provide Medicare with notice: file an 855 Form or use PECOS. The ALJ upheld revocation of the Petitioner's participation in Medicare.

However, a September CRD decision demonstrated that careful record keeping by a provider or supplier could result in reversal of an enrollment revocation decision.[12] Here, the MAC attempted to conduct a site visit of the Petitioner's facility, a home health agency, and on September 25, 2014, notified the Petitioner that based on the attempted on-site review, it was revoking the Petitioner's enrollment effective July 7, 2014, the date of the attempted site visit.[13] The Petitioner asserted that it moved its practice location and had timely notified Palmetto, providing notice five days prior to the move. Palmetto had no record of the Petitioner's change of address notification. However, the Petitioner submitted a number of pieces of evidence in support of its assertion of notification, including employee testimony and other change of address notification submissions. In Decision No. CR 4229, the ALJ found the Petitioner's evidence compelling and reversed CMS' revocation of Medicare enrollment and billing privileges for the Petitioner, concluding that the Peti-

tioner timely reported its change of address to the Medicare contractor.

For the full text of DAB and CRD decisions referenced in these summaries, visit the HHS website.[14]

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1 AHLA's Accreditation, Certification, and Enrollment Affinity Group, of the Regulation, Accreditation, and Payment Practice Group, monitors DAB and CRD decisions relating to Medicare enrollment and provides quarterly summaries of the decisions, *available at* www.healthlawyers.org/Members/PracticeGroups/RAP/memberbriefings/Pages/DAB-and-CRD-Decision-Summaries-Regarding-Provider-Enrollment.aspx.

2 *South Nassau Oncology Practice, P.C. v. Centers for Medicare & Medicaid Services*, Docket No. C-15-3497, Decision No. CR4412, Nov. 6, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4412.pdf.

3 The effective date of Medicare enrollment is the later of: (1) the date of filing of a Medicare enrollment application that is subsequently approved; or (2) the date on which an enrolled physician or non-physician practitioner first began furnishing services at a new practice location. 42 C.F.R. § 424.520(d).

4 *Hartford County Cardiology, PC v. Centers for Medicare & Medicaid Services*, Docket No. C-15-3222, Decision No. CR4400, Nov. 4, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4400.pdf.

5 *Pepper Hill Nursing & Rehab. Ctr.*, DAB No. 2395, at 10 (2011).

6 42 C.F.R. § 424.535(a)(4).

7 *Sandra E. Johnson v. Centers for Medicare & Medicaid Services*, Docket No. C-15-504, Decision No. CR4209, Sept. 10, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4209.pdf.

8 CMS or its Medicare contractor may revoke a supplier's enrollment and billing privileges if the supplier is determined not to be in compliance with enrollment requirements, including the requirement for suppliers to report a change in practice location within 30 days. 42 C.F.R. § 424.516(d)(1)(ii), (iii).

9 *Fares F. Yasin, M.D. v. Centers for Medicare & Medicaid Services*, Docket No. C-15-2655, Decision No. CR4425, Nov. 12, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4425.pdf.

10 *Care Pro Home Health, Inc. v. Centers for Medicare & Medicaid Services*, Docket No. C-15-1362, Decision No. CR4321, Oct. 15, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4321.pdf.

11 *Viora Home Health, Inc. v. Centers for Medicare & Medicaid Services*, Docket No. C-15-2500, Decision No. CR4369, Oct. 27, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4369.pdf.

12 *Adora Healthcare Services, Inc. v. Centers for Medicare & Medicaid Services*, Docket No. C-15-682, Decision No. CR4229, Sept. 18, 2015, *available at* www.hhs.gov/dab/decisions/civildecisions/2015/cr4229.pdf.

13 CMS may perform an on-site review of a provider to verify that the enrollment information submitted to CMS is accurate and to determine compliance with Medicare enrollment requirements; CMS may use the results of the on-site visit to support a decision to deny or revoke a provider's enrollment. 42 C.F.R. § 424.517(a). Home health agencies must report a change of address to the appropriate Medicare contractor within 90 days of the change. 42 C.F.R. § 424.516(e)(2).

14 DAB decisions are *available at* www.hhs.gov/dab/decisions/dabdecisions/index.html, and CRD decisions are *available at* www.hhs.gov/dab/decisions/civildecisions/index.html.

Regulation, Accreditation, and Payment Practice Group Leadership

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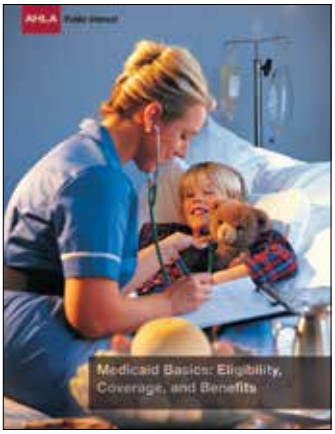

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