



**The Medicare Bundled Payments for Care Improvement Initiative:
An Analysis and Its Implications to Potential Participants**

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Introduction

Recently, the Center for Medicare and Medicaid Innovation (the “**Center**”), a division of CMS created by the Affordable Care Act enacted in 2010, rolled out a new, voluntary bundled payment program, the Bundled Payments for Care Improvement Initiative (the “**Initiative**”) and invited health care providers to apply to participate. The Center is rolling out the Initiative under its authority granted under Section 3021 of the Affordable Care Act, which established the Center with the authority and direction to “test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care” for those who receive Medicare, Medicaid or CHIP benefits. The Initiative is separate and distinct from the National Pilot Program on Payment Bundling that CMS is required to implement by January 1, 2013 under Section 3023 of the Affordable Care Act. The Initiative comes on the heels of the widely disappointing Medicare Accountable Care Organization (“**ACO**”) proposed regulations under the Medicare Shared Savings Program (“**MSSP**”), and the Initiative raises many business, operational, and legal issues that providers will need to consider in determining whether participation will make sense for the organization. This white paper summarizes the provisions of this new program, its payment models, and the legal issues and challenges that will face providers who choose to participate.

The Basics

What is the Bundled Payments for Care Improvement Initiative? The Center launched the Initiative on August 23, 2011 to explore and study four distinct bundled payment models in an effort to achieve better health, better health care, and reduced expenditures. Generally, three of the four payment models (further described below) utilize a “retrospective” payment model in which Medicare makes a discounted traditional fee-for-service payment (to which CMS and the participant have agreed), which is subsequently reconciled against a target price. The fourth payment model uses a “prospective” payment approach, under which CMS makes a single bundled payment to the participating hospital for an entire episode of care in lieu of traditional Part A and Part B fee-for-service payments. Importantly, CMS may permit gainsharing among the participants in all four models. As a corollary, the Secretary may consider waiving applicable federal fraud and abuse laws (discussed in further detail below).

Eligibility to Participate in the Initiative. The Initiative’s Request for Application (“**RFA**”) identifies a number of different entities or organizations eligible to participate (or receive payment awards) in the Initiative (“**Awardees**”). Depending on the applicable payment model, eligible participants range from acute care hospitals, physician group practices, health systems and physician hospital organizations to post-acute providers (such as skilled nursing facilities, long-term care hospitals, inpatient rehabilitation facilities, home health agencies) and “conveners of participating health care providers,” and presumably can include any Part A or Part B provider that furnishes services to a beneficiary during the defined episodic period, in accordance with the particular payment model. The Center uses the new term “conveners of participating health care providers” in the RFA to describe organizations such as state hospital associations or a collaborative of providers. The RFA does not place any eligibility limitations based upon geographic region or the type or size of the health system. Moreover, it makes clear that potential applicants are also encouraged to participate in multiple Medicare payment initiatives (including the Initiative), as well as the Medicare Shared Savings Program, the Pioneer ACO Program, and other medical home and shared savings initiatives. Applicants are also encouraged to partner with State Medicaid programs (such as Medi-Cal) as well as other private payers.

Scope of the Initiative. The Initiative targets all Medicare fee-for-service beneficiaries with Part A and Part B coverage. However, beneficiaries still will retain their freedom to choose health care providers. Nevertheless, those beneficiaries that meet the eligibility requirements of a payment model, and who receive covered care from an Awardee (or participating provider) will be subject to the model’s payment methodology.

The Application Process. Prospective applicants must submit non-binding letters of intent (“LOIs”) and applications to participate in the Initiative by the applicable payment model’s submission deadlines. The Center will not consider an applicant for participation in a model unless the applicant has submitted a timely LOI. Accordingly, prospective applicants should take care to submit the appropriate LOI by the model’s applicable due date, noted below.

Applicants interested in participating in Models 2-4 also may request historical Medicare claims data from CMS to assist the applicants in making target price proposals and redesigning care delivery processes. To receive this information, applicants must also submit a Research Request Packet and (prior to receiving any data) a Data Use Agreement.¹

Applicants may participate in more than one payment model. However, Awardees selected to participate in Model 1 and in Model 2 or 4 will have their Model 1 agreement amended to exclude those MS-DRGs that are included in their Model 2 or 4 agreement to ensure that the same clinical cases are not counted twice and are subject to a single episode payment.

LOI and Application Due Dates. LOIs and applications must be submitted no later than:

	<u>Letter of Intent Due Date</u>	<u>Application Due Date</u>
Model 1: ²	October 6, 2011	November 18, 2011
Models 2-4:	November 4, 2011	March 15, 2012

The Scoring of the Application and Duration of Agreement. The Center will screen applicants for Medicare payment eligibility and, if deemed eligible, will then score applications based on criteria which include (i) model design, (ii) the financial model (*i.e.*, the overall savings to Medicare), (iii) quality of care and patient centeredness; and (iv) the organizational capability, prior experience, and readiness of the particular applicant.

¹ The Center’s Bundled Payments for Care Improvement webpage can be found at <http://innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html>. Potential applicants are encouraged to visit this webpage to access information such as the LOI and application templates, pertinent instructions, a General Fact Sheet, Frequently Asked Questions and other relevant information. All LOIs and Applications must be submitted no later than 5:00 p.m. EDT on the applicable model submission date to BundledPayments@cms.hhs.gov. All Research Request Packets and Data Use Agreements must be submitted to this same email address no later than 5:00 p.m. EDT on November 4, 2011.

² On September 15, 2011, the Center revised and extended the original due dates for Model 1 LOIs and applications, which previously were due on September 22, 2011 and October 21, 2011, respectively.

The Initiative's agreements will include a performance period of three (3) years, with the possibility of extending this initial performance period for an additional two (2) years.

Withdrawal from the Initiative. Because the LOI is non-binding, an applicant who has submitted only an LOI (and not yet submitted an application) to the Center presumably may withdraw from consideration for participation in the Initiative without penalty. In addition, the RFA also contains a procedure for applicants to request the withdrawal or amendment of a previously submitted application. However, it is unclear whether the Center is under any obligation to accept such a withdrawal or amendment. Once an Awardee receives and executes an agreement, the provisions of the agreement likely will govern the circumstances (if any) under which an Awardee can terminate its participation in the Initiative. Accordingly, Applicants should give careful consideration to the manner and conditions upon which a participating provider can withdraw from participation once an agreement has been awarded, as well as the potential effects that such a withdrawal or withdrawals might have on the Awardee's overall ability to participate in the Initiative (*i.e.*, under other Models to which the Awardee may have applied or may apply in the future, or under the Initiative at all).

Awardees Will Be Required to Bear Risk of Loss. In addition to giving Medicare a pre-set discount on payment, all four of the Initiative's models require the Awardee (or some other participating entity) to assume, in varying degrees depending upon the model, financial liability for Medicare payments that exceed established targets or trended historical comparisons with respect to aggregate Medicare payments. All applications are required to identify a single legal entity that will be financially responsible for these "excess" Medicare payments, and include information regarding the responsible party's ability to repay Medicare. This information must also include some form of enforceable assurance in favor of Medicare of the responsible party's ability to repay, such as an irrevocable letter of credit for the full amount of risk. It is unclear, however, how exactly the "full amount of risk" can or will be calculated or estimated. Unlike the MSSP (better known as the Medicare ACO program), downside financial liability under the Initiative is not subject to caps or corridors; *i.e.*, Awardees will be liable for the full amount of Medicare expenditures in excess of the risk threshold.

Program Monitoring. Awardees will be required to fully comply with CMS' (or its contractor's) monitoring and requests for evaluation and information. Awardees should anticipate that requests for information will include information regarding providers, beneficiaries, inter-provider agreements, and participation in surveys and interviews. There also likely will be ongoing monitoring efforts by CMS that include requests for data on cost savings, incentive payments, clinical quality, and patient experience. The RFA makes clear that CMS expects applicants to propose other monitoring measures to improve health care quality and efficiency.

All four models require Awardees to have received the full inpatient prospective payment system ("IPPS") and outpatient prospective payment system ("OPPS") annual payment update for reporting quality measures to CMS since at least the fiscal year 2008 and calendar year 2009, respectively. Hospitals will be required to continue to participate in all CMS quality reporting initiatives during the Initiative's duration. Participating physicians must continue to participate in all quality reporting initiatives in which they already participate. Participating providers are also expected to maintain or improve their performance on the measures reported through the Hospital Inpatient Quality Reporting Program, the Hospital Outpatient Quality Data Reporting Program, and the Physician Quality Reporting System, during the Initiative's duration. As further discussed below, participants

in Model 1 will have to meet all applicable Hospital Inpatient Quality Reporting requirements. The RFA is silent regarding the specific quality reporting measures that participants in Models 2, 3 or 4 will be required to report. The RFA notes that these reporting requirements will be proposed in the future, and applicants should expect to be required to agree to a standardized set of quality reporting measures. It is not clear from the RFA, however, whether the standardized reporting measures will be limited to the specific MS-DRGs included in the defined episode, or whether they will be more broad-based reporting measures.

CMS May Terminate the Initiative Agreement. The RFA makes clear that CMS reserves the right to review the participation status of an Awardee, and terminate an Awardee's agreement for any of the following reasons:

- Failure to meet quality standards;
- Demonstration during the post-episode monitoring period of consistently increased Medicare expenditures for services within the episode;
- Failure to comply with applicable fraud and abuse laws (*e.g.*, civil monetary penalty statute, anti-kickback statute, physician self-referral prohibition, etc.);
- Restriction of access to medically necessary care;
- Failure to repay money owed to Medicare as specified in an Awardee's agreement;
- Failure to satisfy conditions of participation; and
- Inability of CMS to continue funding the Initiative.

Beneficiary Protections. The Initiative includes protections designed to alert patients of their participation in the Initiative. Awardees will be required to notify patients of their participation in the Initiative, as well as the fact that the patient is entitled to seek care from any provider of his or her choosing. Awardees will have to provide this patient notice through means that include signage, individual notices, or other means of patient notification approved by CMS. Notices must be provided to patients prior to or as soon as possible after the initiation of an episode, and must describe the goals of the Initiative and the use of financial incentives. Patients will also be informed that CMS may contact them to provide feedback for evaluation of the Initiative. Moreover, unlike the ACE Demonstration Project (which permits providers to offer certain financial incentives to beneficiaries), providers participating in the Initiative will not be permitted to share savings with beneficiaries under any of its payment models.

Summary of Bundled Payment Models

The Initiative, as discussed above, introduces four distinct bundled payment models for study in an effort to improve health care while reducing expenditures. Importantly, the Center notes in its RFA that the Initiative is the first in a series of anticipated activities that will focus on care episode redesign. Accordingly, in addition to the models described in this white paper, providers can anticipate the Center to introduce (i) future **prospective** payment models with respect to acute-care hospital plus post-acute-care episodes, and post-acute care only episodes, as well (ii) both retrospective **and** prospective payment models with respect to chronic care. The remainder of this section summarizes the current four payment models introduced by the Center's Initiative.

Model 1: Retrospective Acute Care Hospital Stay Only. Payment Model 1 involves an episode of care that is focused solely on acute-care inpatient hospitalization. Under this model, the episode begins with a patient's hospital admission and ends upon the patient's discharge. It includes

all Part A services furnished to a patient during his or her hospital stay, including hospital diagnostic testing and all related therapeutic services furnished by an entity wholly-owned or operated by the admitting hospital in the three (3) days prior to admission (*i.e.*, services subject to the Medicare 3-day window payment bundling rule).

Model 1 requires hospitals to take on substantial risk. It is important to note that this payment model includes all Medicare fee-for-service patients that are treated in a participating hospital, regardless of the particular MS-DRG. Accordingly, hospitals participating in Model 1 cannot include or exclude particular patient types from Model 1 based upon a specific service or condition. In addition, unlike Models 2-4, Model 1 does not appear to contemplate any risk adjustment methodologies in setting a target price for the bundled payment, and so applicants will need to take acuity mix into account when proposing the percentage discount off of base MS-DRG payments. Hospitals may share gains (in all years of the Model 1 agreement) beyond the negotiated MS-DRG payment discount with physicians and other personnel who treat patients during the episode. However, gainsharing arrangements must be approved by the Center and are subject to waiver by the Secretary of applicable fraud and abuse laws, as discussed more fully below. Moreover, participation in any gainsharing arrangement (in all four of the Initiative's payment models) must be purely voluntary.

The Center expects applicants to offer Medicare a discount on Part A hospital inpatient payments (specifically base MS-DRG payments), which the applicant should calculate to include all payment adjusters and outlier payments (except DSH payments, hospital capital payments, and IME payments). CMS will apply the discount to payment rates going forward, as such rates are updated (up or down) according to standard annual IPPS updates or adjustments. These adjustments likely would include, without limitation, any adjustments to a hospital's IPPS rates under CMS' Value-Based Purchasing rules, CMS' Hospital Acquired Condition payment provisions, as well as under the Medicare Hospital Readmissions Reduction Program ("**HRRP**"), which will penalize a hospital for readmissions above certain thresholds for specified conditions beginning October 1, 2012.³ Accordingly, applicants (in all models) should take care to consider all of the potential payment incentive and penalty programs that could impact the MS-DRG payments.

The Center is expected to require, at minimum, a phased discount as follows:

- Applicants may offer a discount of 0% or higher during first six months of Year 1;
- Applicants are expected to offer a minimum discount of 0.5% during the last six months of Year 1;
- Applicants are expected to offer a discount of 1% during Year 2; and
- Applicants are expected to offer a discount of 2% during Year 3.

However, applicants are encouraged by the Center to offer greater discounts than the minimum discounts noted above. Medicare will continue to process Part A claims under Model 1 under existing IPPS payment rules, and will reduce such claims by the applicable discount before making payment to the Awardee. Physicians' traditional fee-for-service payments will remain unaffected by Model 1.

³ See 42 U.S.C. § 1395ww(q); *see also* 76 Fed. Reg. 51476, 51660-51676 (Aug. 18, 2011) (Final Rule implementing portions of the HRRP for fiscal year 2012).

As noted above, hospitals that participate in Model 1 will be subject to all of the Hospital Inpatient Quality Reporting Program measures, including those Hospital IQR reporting measures that are not required for the full annual payment update. Hospitals that participate in Model 1 should also expect these reporting requirements to be updated during the course of their agreement with the Center to reflect the then current Hospital IQR reporting measures in order to account for the addition or retirement of reporting measures over time.

Monitoring and Payment Reconciliation Under Model 1. Because the payment made to the Awardee already will incorporate the negotiated discount, there will be no further episode reconciliation by Medicare against the target price under Model 1. However, Medicare will monitor overall Part A and Part B expenditures during both the episode and during a thirty (30) day post-episode monitoring period. **This monitoring will include Medicare expenditures for included beneficiaries at non-participating providers.** With respect to both episode and post-episode monitoring, Awardees will be required to repay Medicare for the difference between Medicare Part A **and Part B** payments that exceed trended historical aggregate Part A and Part B payments beyond “risk thresholds” during the episode or post-episode monitoring period, as applicable.

The RFA is very unclear about where or how CMS will set these risk thresholds and how they will be applied. The language of the RFA suggests that a risk threshold will be set separately for the episode and the post-episode period, but it is unclear whether aggregate expenditures would be “reset” for the post-episode monitoring, or whether the aggregate expenditures would continue to accrue through the episode and post-episode monitoring period, measured at two points in time (*i.e.*, end of episode and end of post-episode monitoring period). In addition, the RFA is unclear in Model 1 (and in Models 2-4) whether post-episode monitoring will include all Part A and Part B expenses, or whether the post-episode monitoring will exclude “unrelated” expenses (the way the episode reconciliation will in Models 2-4). The definition of “Post Episode Monitoring” in Appendix A of the RFA suggests that such monitoring is aimed at detecting expenditures “expected to be included in an episode of care that are furnished/paid outside of the episode...thereby potentially increasing total Medicare spending for services related to the episode” (emphasis added). This language suggests that post-episode reconciliation will exclude services designated as “unrelated,” but the scope of post-episode expenditures that will be included is unclear in all of the model descriptions. This distinction is less of an issue in Model 1 than the other models, because Model 1 includes all Part A and Part B expenses for included beneficiaries, irrespective of assigned MS-DRG, but this distinction could have more material consequences under Models 2-4.

Moreover, while the RFA provides that the risk thresholds will be set “account for random variation,” the RFA is silent regarding whether the risk thresholds will be risk-adjusted to account for a particular participating provider’s acuity mix. As noted above, unlike Models 2-4, Model 1 does not contemplate the use of risk adjustment methodologies in setting the target price, and so while unclear, we believe it unlikely that the Initiative would apply risk adjustment to the risk thresholds under this Model. Finally, the RFA also does not specify whether reconciliation will be conducted on a case-by-case (*i.e.*, individual beneficiary) basis, or on an aggregate basis (*i.e.*, discharges where the thresholds are exceeded would be offset by discharges where thresholds are not exceeded).

Model 2: Retrospective Acute Care Hospital Stay Plus Post-Acute Care. Model 2 extends the episode of care to include both acute-care hospitalization and post-acute care following and

associated with the acute-care episode. Additionally, unlike Model 1, Model 2 includes physician and other Part B services associated with the episode.

Under Model 2, the episode begins with a hospital admission for an agreed upon MS-DRG, and continues for a minimum of thirty (30) days following the patient's discharge from the hospital. Unlike in Model 1, applicants will have some flexibility to select which service or condition (by MS-DRG) is included in their Model 2 agreement. Applicants also will have discretion to choose between two different options with respect to the end of the episode. If an applicant chooses Option 1, the episode under Model 2 will end between thirty (30) and eighty-nine (89) days after hospital discharge. If an applicant chooses Option 2, the episode under Model 2 will end a minimum of ninety (90) days after hospital discharge.

The episode under Model 2 will include all Part A and Part B services furnished during the hospital stay and Part A and Part B services related to the episode anchor that are furnished during the post-discharge period. The episode also will include all Part A services for related readmissions and all related Part B services furnished during the "post-discharge period" (defined in the application as 30 to 90+ days post-discharge), including during related and unrelated admissions. It is unclear from the RFA whether the Initiative will use the broad definition of "related" readmissions under the HRRP (*i.e.*, any readmission), or whether some alternative test for relatedness will apply. Language in the RFA suggests that services will be considered related unless otherwise specified; under Models 2-4, "related readmissions" are defined as excluding Part A services identified by MS-DRGs "designated as unrelated," and also as excluding unrelated Part B services identified by principal ICD-9 diagnosis codes "designated as unrelated." Accordingly, the RFA language suggests that relatedness under the Initiative may be subject to different standards than under the HRRP, and that applicants will need to expressly define in their applications how to identify Part A and Part B services that will be "designated as unrelated." Whichever approach the Center ultimately adopts is likely to apply to all similarly-situated models; *i.e.*, models that include "related" admissions in evaluating total Medicare expenditures (*e.g.*, Models 2, 3, and 4). All hospital diagnostic testing and all related therapeutic services furnished by an entity wholly-owned or operated by the admitting hospital during the three (3) days prior to hospital admission also will be included.

All eligible beneficiaries for the episode (based on MS-DRG) admitted to the Awardee, or its participating providers, must be included. Awardees may share gains with all providers treating patients during the episode. However, as with Model 1, any gainsharing will be subject to applicable fraud and abuse laws (and the scope of any waiver of such by the Secretary) and participation in any gainsharing arrangement must be purely voluntary.

The Center expects applicants that participate under Option 1 to offer Medicare a minimum three percent (3%) discount off of all included MS-DRGs and other Part A and Part B services provided during the episode. Due to a longer episodic duration, the Center only expects applicants that participate under Option 2 to offer Medicare a minimum two percent (2%) discount.

The target price for the episode will include a single rate of discount on the expected Medicare payments for all included Part A and Part B services. Applicants should calculate the inpatient hospital payment portion of the target price to include all payment adjustors and outlier payments (except DSH payments, hospital capital payments, and IME payments). CMS will consider applicant proposals using risk adjustment which include a description of the methodology. CMS will apply the discount to payment rates as such rates are updated (up or down) according to standard

annual IPPS updates or adjustments. The negotiated discount will remain constant while the target price is indexed each year to fee-for-service payment changes (up or down) according to applicable standard IPPS, the Physician Fee Schedule (“PFS”) and post-acute provider prospective payment system updates or adjustments, presumably including any adjustments under the HRRP. All claims for services will continue to be processed under relevant IPPS, PFS and post-acute payment system rules. Finally, because Part B services are being paid under this model at a pre-determined discount, the beneficiary’s Part B copayment amount will presumably be proportionately reduced or discounted.

Monitoring and Payment Reconciliation Under Model 2. Unlike in Model 1, there will be episode reconciliation against the target price under Model 2. In the event that the aggregate fee-for-service payments paid by Medicare for “included services” (*i.e.*, services not specifically designated by MS-DRG or ICD-9 as unrelated), are less than the target price, Medicare will pay the Awardee the difference. If, however, the aggregate fee-for-service payments paid by Medicare for included services exceed the target price, the Awardee will pay the difference to Medicare. Moreover, Medicare also will monitor Part A and Part B expenditures during a thirty (30) day post-episode monitoring period. This monitoring will include Medicare expenditures for included beneficiaries at non-participating providers. Awardees will be required to repay Medicare for any difference between Medicare Part A **and Part B** payments that exceed trended historical aggregate Part A and Part B payments beyond a risk threshold during the post-episode monitoring period. As with Model 1, the RFA is unclear how or where the post-episode risk threshold will be set, and is unclear whether services “designated as unrelated” during the episode will continue to be excluded during the calculation of expenditures during the post-episode monitoring period. Presumably, readmissions following the thirty (30) day post-episode monitoring period would be excluded from reconciliation.

Model 3: Retrospective Post-Acute Care Only. Model 3 limits the episode of care to only post-acute care following an acute inpatient hospital stay. The episode under Model 3 begins with the initiation of post-acute care services at a skilled nursing facility, inpatient rehabilitation facility, long-term care hospital, or home health agency within thirty (30) days of the patient’s discharge from an acute care hospital for an agreed upon MS-DRG. The discharging acute care hospital can be any hospital and need not be an Awardee or a participating provider. The episode includes all related Part A and Part B services furnished during the episode period (defined in the application as 30+ days from the episode anchor), including related readmissions. The episode also will include all Part A services furnished during related readmissions and all related Part B services furnished during the episode period, including during any readmission (related or unrelated). Because the episode anchor is the admission to the participating post-acute provider within thirty (30) days of discharge from the acute care hospital, the episode would not include post-acute care rendered by non-participating providers after discharge from the acute care hospital but prior to the admission to the participating post-acute provider.

The episode under Model 3 ends a minimum of thirty (30) days following the episode anchor (*i.e.*, admission to the participating post-acute care provider), but the exact duration of the episode is to be proposed in the application. CMS will give preference to applications that propose an episode definition longer than thirty (30) days, because CMS wants to understand “how care redesign extends to the beneficiary’s transition back into the community.”

All eligible beneficiaries who initiate post-acute care services with the Awardee or its participating providers must be included in the episode. Awardees are also permitted to share gains with providers treating patients during the episode, although as previously noted, participation in gainsharing arrangements must comply with applicable fraud and abuse laws and must be purely voluntary.

The Center does not include a suggested discount rate for Model 3 in the RFA. However, as with Model 2, CMS expects applicants to propose a target price for the episode that includes a single rate of discount for all included services. When calculating the target price, applicants should factor in projected readmissions and outlier payments. No outlier payments beyond the usual fee-for-service payments that would have been paid for qualifying cases will be made above the target price. CMS will consider applicant proposals using risk adjustment which include a description of the methodology and plans for updating risk adjustment on a yearly basis based on new information. The negotiated discount reflected in the target price will remain constant as the target price is indexed each year to fee-for-service payment changes according to applicable PFS and post-acute provider prospective payment system updates and adjustments.

Medicare will continue to process claims under the applicable PFS, post-acute provider, or other supplier or provider system or rules. Finally, because Part B services are being paid under this model at a pre-determined discount, the beneficiary's Part B copayment amount will presumably be proportionately reduced or discounted.

Monitoring and Payment Reconciliation Under Model 3. Like Model 2, there will be episode reconciliation against the target price under Model 3. In the event that the aggregate fee-for-service payments Medicare paid for included services rendered during the episode are less than the target price, Medicare will pay the difference to the Awardee. If, however, the aggregate fee-for-service payments for included services exceed the target price, the Awardee will pay the difference to Medicare. Additionally, Medicare also will monitor Part A and Part B expenditures during a thirty (30) day post-episode monitoring period. Awardees will be required to repay Medicare for any difference between Medicare Part A **and Part B** payments that exceed trended historical aggregate Part A and Part B payments beyond a risk threshold during the post-episode monitoring period. As with Model 1, the RFA is unclear how or where the post-episode risk threshold will be set, and is unclear whether services "designated as unrelated" during the episode will continue to be excluded during the calculation of expenditures during the post-episode monitoring period. Presumably, readmissions following the 30-day post-episode monitoring period would be excluded from reconciliation.

Model 4: Prospective Acute Care Hospital Stay Only. Model 4 is the final payment model introduced under the Initiative. Model 4 includes both Part A services and physician and other Part B services furnished during the episode of care.

Model 4 raises several challenging questions. Under Model 4, the episode of care involves only the "acute inpatient hospital stay." Like Model 1, the episode begins upon the patient's hospital admission. However, the RFA is very unclear about when a Model 4 episode ends. First, the RFA indicates that the episode ends upon discharge from the acute care hospital and includes all Part A and Part B services furnished to the patient during his or her hospital stay, including services subject to the Medicare 3-day window payment bundling rule (*i.e.*, hospital diagnostic testing and all related therapeutic services that are furnished by an entity wholly-owned or operated by the admitting

hospital in the three (3) days prior to admission). But language immediately following this description indicates that for Model 4, like Models 2 and 3, any Part A services furnished during “related readmissions” and all “related” Part B services furnished during any readmission (related or unrelated) are “also included in the episode payment.” If the episode ends upon discharge, how could the episode include related readmissions? Other sections of the Model 4 summary indicate that there will be a “post-discharge period,” the duration of which the applicant is expected to propose, during which “related readmissions” will be included in the episode. This to-be-proposed “post-discharge period” appears to be distinct from the “post-episode monitoring period,” which is set at a predetermined thirty (30) days “post-hospital discharge.”⁴ Thus, the RFA description of Model 4 is unclear about the definition of the “episode.” It appears that the Model 4 episode likely was intended to be defined as beginning with admission to the acute care hospital, and ending at some minimum number of days (to be proposed in the application) following acute care hospital discharge. Hopefully, the Center will clarify the Model 4 episode definition in response to comments from the provider community.

In contrast to Model 1’s all inclusive approach with respect to eligible Medicare beneficiaries, only beneficiaries treated in a participating hospital for agreed-upon MS-DRGs are included in Model 4. In addition, while Model 1 only includes a bundled payment with respect to Part A services, Model 4 includes a single prospective bundled payment for both Part A and Part B services. As with all of the Initiative’s models, gainsharing arrangements are permitted, subject to necessary waivers to fraud and abuse laws. Participation in gainsharing under Model 4 (as is the case in all models) also must be purely voluntary.

CMS expects applicants to propose a target price for the episode that includes a single rate of discount off the expected Medicare Part A and Part B payments for all hospital facility and professional services furnished during the episode and related readmissions for the agreed-upon MS-DRG. With respect to the Part A inpatient portion of the bundled payment (specifically base MS-DRG payments), the applicant’s proposed payment should consider all payment adjustors and outlier payments (except DSH payments, hospital capital payments, and IME payments). Model 4 permits applicants to include proposals around risk adjustment, which must include a description of the methodology and which may include plans for updating risk adjustment on a yearly basis, based on new information. Model 4 also permits applicants to include MS-DRGs that were included in the ACE Demonstration Project, but based upon the discounts established during the Project, the RFA makes clear that the Center expects applicants to offer a minimum discount that is greater than three percent (3%). The negotiated bundled payment rate will be indexed to fee-for-service payment changes as they are updated (up or down) annually according to applicable PFS and IPPS updates and adjustments, presumably including any adjustments under the HRRP.

Medicare will pay the single bundled payment directly to the hospital (whether or not the hospital is the Awardee or participating organization) where the patient was treated. The single bundled payment will be paid following claims submission at the time of discharge. Nevertheless, the Awardee (whether it is the hospital or a convener) will bear the full risk for the price of the episode. Physicians will be paid by the hospital for their professional services, which payment can be at their usual fee-for-service rate, or at another negotiated rate proposed by the applicant. For record

⁴ The RFA suggests that this post-discharge window should be a minimum of thirty (30) days.

keeping purposes, claims for professional services included in the Model 4 episode will still be submitted by the physician to Medicare, but these claims will not be paid by Medicare and will be processed as “no pay” claims.

Moreover, instead of the standard Part B coinsurance payment, patients will pay a fixed Part B copayment. The amount of the copayment will vary by MS-DRG and by hospital. The amount will be calculated based on the typical coinsurance of twenty percent (20%) on each Part B claim for each MS-DRG that is included in the bundled payment, regardless of the nature or amount of actual services rendered to any individual patient. While the RFA is not clear, presumably the patient will pay the fixed copayment to the hospital, which would in turn distribute it to participating Part B providers in accordance with the terms of the agreements between the hospital and the Part B providers. Presumably the shift to a fixed copayment approach is to account for the fact that Part B claims are included in the prospective bundled payment, and therefore, will no longer be paid separately by Medicare. Interestingly, this approach appears to be in conflict with the clear protection of a patient’s freedom of choice provided by the Initiative because it creates an apparent economic barrier for those patients that elect to go outside the “network” of participating providers, since they will presumably be required to pay non-participating providers another Part B copayment in addition to the fixed Part B copayment already paid.

The RFA does not specify how non-participating providers that furnish services to a patient during a Model 4 episode, whether a physician or another hospital with respect to a readmission, will know to bill the primary admitting hospital. Assuming the episode definition under Model 4 includes some to-be-proposed “post-discharge period,” it is unclear (1) how non-participating providers’ claims would be processed; (2) if those claims are denied as being already included in an episode, how non-participating providers would pursue payment from the Awardee and at what rate they would be paid (if at all); and (3) if those claims are paid by Medicare but should not have been paid because they were miscoded, not medically necessary or for some other reason, how an Awardee could or would pursue restitution from non-participating provider (*i.e.*, because the Awardee will be responsible for reimbursing Medicare for any such paid claims under Model 4). While the RFA indicates that the MAC will have a list of awardees and participating providers, as well as a list of included MS-DRGs and negotiated rates, the claims reconciliation process under Model 4 appears very complicated.

Monitoring and Payment Reconciliation Under Model 4. As with Models 2 and 3, there also will be episode reconciliation (if any) against the target price under Model 4. The Awardee must repay Medicare for any separately paid Part A claims furnished during the episode, any separately paid Part B claims furnished during the episode, and any Part B claims for related Part B professional services furnished during any readmission (whether or not the readmission is related). Presumably, an Awardee should not be required to repay Medicare for claims that Medicare pays in error (*i.e.*, claims by participating providers that have already been paid by the hospital or Awardee). Prospective applicants should take care to address this potential issue in their application materials and in any final agreements with the Center and/or participating providers. In addition, Medicare will monitor Part A and Part B expenditures during a thirty (30) day post-episode monitoring period. The Awardee will be required to repay Medicare for the difference between the Part A **and Part B** payments that exceed trended historical aggregate Part A and Part B payments beyond a risk threshold (taking into account the discounted bundled payment) during the post-episode monitoring period.

Regulatory Issues Raised By the Initiative

Participation in the Initiative raises many difficult and complex healthcare regulatory issues, under both federal and state laws. CMS can waive application of some (but not all) of the federal laws, but other federal laws still apply, as well as a number of state laws, which CMS does not have authority to waive. The section below discusses the potential application of these legal issues to participants in the Initiative.

Federal Law Issues for Which Waiver is Available. CMS has authority to waive the application of certain Medicare and Medicaid fraud and abuse laws “as may be necessary” to develop and implement the Initiative. However, the manner and scope of that waiver is unclear, and applicants presumably will have to seek further clarification through the application process to resolve this uncertainty.

The waiver approach taken here contrasts sharply with the approach taken with the proposed ACO regulations. For ACOs, very specific guidance was provided and the guidance covered more legal issues. For example, in addition to CMS, the OIG issued ACO guidance. Also, the Internal Revenue Service provided ACO guidance for tax-exempt organizations and the Department of Justice and the Federal Trade Commission issued guidance for ACOs on antitrust issues. Here, by comparison, there is little guidance on how a waiver of Medicare and Medicaid fraud and abuse laws will work. Although the concept of a waiver is discussed in the RFA, there are no specifics provided, and the scope of any potential waiver is more limited, because antitrust and tax-exempt organization issues are not addressed at all. While CMS has explained that it “will consider exercising [its] waiver authority with respect to the fraud and abuse laws” and “may also consider waiving additional provisions” of the Medicare Act, it offers no detail as to the process it will follow in waiving application of these laws or the proposed scope of any such waiver(s). Thus, there is, for now, no blanket or systematic waiver, and hence the potential inference is that each applicant should specifically request a waiver of whatever Medicare and Medicaid fraud and abuse laws it deems appropriate, when submitting its application to participate in the Initiative, and presumably explain the reason for its request.

The Civil Money Penalty (“CMP”) Statute. The closest CMS has come to a blanket waiver is with respect to the provision of the CMP statute prohibiting payments from hospitals to physicians to reduce or limit services to Medicare or Medicaid beneficiaries under the physician’s care. Traditionally, the federal government interprets this CMP provision to prohibit “gainsharing” programs (*i.e.*, programs that provide financial incentives to physicians to lower hospital costs, typically by sharing with the physicians a portion of the cost savings achieved).

In the RFA, CMS indicated that gainsharing will be permitted by Initiative participants, and it has set out a number of parameters (both general and specific) that these gainsharing programs must follow. These parameters, for example, specify that the compensation to be shared with the physicians cannot exceed 50% of the total savings achieved under the bundled payment program, and cannot exceed 50% of what the physicians are normally paid for the cases that are included in the gainsharing initiative. Also, as noted above, physician participation in the gainsharing must be “voluntary” (*i.e.*, physicians cannot be required to participate or be subjected to “adverse consequences” if they choose not to participate), and, not surprisingly, physicians may not reduce or limit services to Medicare beneficiaries that are “medically necessary.” Parameters, among other

things, also address the need for minimum quality requirements and the need to monitor quality performance.

CMS indicates that applicants will have to describe their proposed gainsharing programs in detail. Presumably, if an applicant is accepted into the Initiative, then the CMP statute is waived as to that applicant's gainsharing program, if it is operated as described in the application. However, this has not been made explicit. Also, whether and how a waiver from the Stark law and/or the federal anti-kickback statute will be granted to a participant's gainsharing program (and/or other financial arrangements with referring physicians) has not been explained.

The Stark Law. The Stark law prohibits a physician from referring Medicare patients to an entity, such as a hospital, for certain "designated health services," including all inpatient and outpatient hospital services, if the physician has a financial relationship with the entity (unless an exception applies). Accordingly, the Stark law will be violated unless all of the financial relationships between and among the referring physicians and the other providers participating in a bundled payment program (such as the Initiative) meet applicable Stark law exceptions, or CMS grants a waiver. However, CMS does not directly address whether or not it will issue waivers of the Stark law.

Presumably, an applicant can request a waiver of the Stark law for its proposed financial arrangements, but it is uncertain whether and how such a request would be granted, or if it would be conditional, *e.g.*, only if compensation is fair market value. Potentially, therefore, participants might need to rely on existing Stark law exceptions to protect their financial relationships with referring physicians, such as those for personal services arrangements or fair market value compensation. Unfortunately, it may be difficult to shoehorn innovative, incentive-based compensation arrangements, including the payment of shared savings based on cost reductions achieved, into the existing Stark law exceptions, given that they were designed years ago to suit more traditional compensation approaches.

The Anti-Kickback Statute. The federal anti-kickback statute prohibits the offer, payment, solicitation or receipt of remuneration, directly or indirectly, overtly or covertly, in cash or in kind, as inducement for the referral of patients or arranging for the referral of patients to receive services for which payment may be made in whole or in part under a federal health care program. Accordingly, the federal anti-kickback statute is potentially implicated to the extent any of the financial relationships between and among the participants in the Initiative are intended to induce referrals. Further, CMS has provided no indication as to whether it intends to grant any waivers of the federal anti-kickback to Initiative participants.

Presumably, an applicant can request a waiver of the federal anti-kickback statute to its proposed arrangements, but it is uncertain whether and how such a request would be granted. In the absence of a waiver, participants would be subject to complying with the federal anti-kickback statute, potentially including attempting to satisfy a regulatory "safe harbor" to the extent one is available, in an effort to protect their arrangements. Fortunately, because the federal anti-kickback statute is intent-based, the intent requirement should potentially reduce the risk of a violation, especially to the extent that the participants in the bundled payment arrangement develop and use commercially reasonable arrangements, motivated by legitimate efforts to improve the quality and efficiency of the healthcare they deliver, rather than to induce referrals or other health care business.

Federal Law Issues for Which No Waiver is Available. CMS lacks authority to waive the application of numerous federal laws that are outside of its jurisdiction, and hence these other federal laws will apply, and therefore may represent a significant hurdle to the implementation of the Initiative. Participants must be mindful of these other federal laws, such as antitrust and tax laws, in connection with their participation in the Initiative, and must proceed with caution to ensure compliance.

Antitrust Laws. In marked contrast to the situation facing participants in ACOs, those participating in the Initiative will not have the benefit of a federal antitrust law “safety zone” nor will they have the burden of needing to obtain an antitrust law determination from a federal enforcement agency, in order to be accepted by CMS into the Initiative. Instead, participants will be in the same situation in which providers generally find themselves when structuring a new business or entering a new service line in collaboration with other providers, some of whom may be viewed as actual or potential competitors, from an antitrust standpoint. In other words, they will be subject to complying with the law, and must either make their own determination that their conduct is and will be compliant, or seek their own guidance from the applicable regulatory agencies to review their proposal.

In assessing their proposal against the requirements of antitrust law, providers will need to analyze all potential antitrust issues that might be raised as a result of their collaborations, developed as part of the Initiative. For example, the relative market shares of participants, the extent to which there will be agreement among participants on price-related terms and conditions, the degree of their proposed clinical and financial integration, the extent to which any joint activities and collaboration are necessary to create the pro-competitive benefits in the marketplace they are seeking to achieve, and the overall potential pro-competitive and anti-competitive effects of their arrangements on the marketplace will need to be carefully assessed. They will also want to carefully analyze the extent to which they may share competitively-sensitive information or agree to engage in collaborative conduct beyond the scope of the bundled payment arrangement itself.

Tax-Exempt Issues. Participation in the Initiative could also potentially raise a number of issues for tax-exempt hospitals. For example, tax-exempt hospitals will want to know that participation will not result in private inurement, more than incidental private benefit, or unrelated business income, all of which can result in significant adverse consequences for a tax-exempt hospital. In contrast to the Medicare ACO program, the IRS has not provided any guidance as to its proposed treatment of participants in the bundled payment program.

Accordingly, tax-exempt hospitals and potentially other tax-exempt entities (such as community clinics or medical foundations) who are considering participating in the Initiative in conjunction with “insiders” of such tax-exempt entities must comply with current tax-exempt rules, and will have no special guidance to rely on here. Relationships between “insiders” and tax-exempt entities are subject to additional scrutiny and regulation to prevent private inurement and non-incidental private benefit, and this will be particularly relevant for tax-exempt hospitals, as many of the physician medical staff leaders who may be deemed to insiders of the hospital, would also be logical partners in any bundled payment program.

In the absence of specific IRS guidance, tax-exempt hospitals presumably must structure their arrangements in such a way so that they would be unlikely to result in private inurement, non-incidental private benefit and unrelated business income, under existing IRS standards. In order to

achieve this, tax-exempt hospitals presumably would follow the general guidance regarding other joint ventures, which involve insiders, such as ancillary service ventures, ambulatory surgery centers, and other joint ventures. Thus, tax-exempt hospitals should consider maintaining majority control of the governance of and profit participation of any entity formed to participate in the Initiative, as well as ensuring that the organizational documents of such an entity provide for covenants that are consistent with the tax-exempt hospitals' charitable purposes.

State Law Issues. CMS has no authority to preempt the application of state laws to Initiative participants. Accordingly, state regulatory schemes still apply, and participants must comply with these laws. For example, many states have anti-kickback statutes or self-referral prohibitions that are similar to, but not identical to, the Stark law or the federal anti-kickback statute. Thus, participants must take into account and comply with these state laws when structuring and operating their initiatives, because qualifying for a CMS waiver for the Stark law, the federal anti-kickback statute, or the CMP statute will not necessarily mean that an arrangement complies with comparable state laws. Similarly, some states have strong corporate practice of medicine prohibitions, which may restrict the ability of a lay entity to influence or control the delivery of health care. These prohibitions stand in tension with the goals of Initiative; because one of the purposes is to implement evidence-based medicine standards and impose those standards on participants. As a result, state laws may pose additional obstacles to those participating in the Initiative.

Corporate Practice of Medicine Prohibition. Some states have a prohibition on the corporate practice of medicine, which prohibits lay entities from owning or controlling the practice of medicine, with limited exceptions. The prohibition may also be violated where a lay entity exerts an impermissible level of control over a physician's medical judgment, or where a lay entity profits directly from a physician's practice of his or her professions. Also, the prohibition can be violated if a lay entity holds itself out as providing, or bills for the provision of physician services.

We anticipate that most Awardees will be lay entities. In particular, any Awardee that includes hospitals as an owner will almost certainly be a lay entity that is prohibited from practicing medicine. However, Awardees will be required to engage in activities which may be characterized as practicing medicine. For example, the adoption of clinical guidelines, and the imposition of such guidelines on physicians participating in the Initiative, arguably could be viewed as exerting a level of control over a physician's clinical judgment and therefore constituting the practice of medicine. Likewise, if a lay entity Awardee receives payment from the Medicare program that includes payment for physician services, and then in turn pays physicians a portion of that payment for their services, the lay entity could be viewed under the law of certain states as providing physician services in violation of the corporate practice of medicine prohibition. Accordingly, bundled payment programs should be very carefully structured and operated to avoid violating the corporate practice prohibition.

State Anti-Kickback Laws. Many states have statutes that prohibit payments for patient referrals. As discussed above, any waiver of the federal anti-kickback statute with respect to participants will apply only as to the federal statute. There is no assurance that these participants' activities and financial relationships will be found to comply with corresponding state laws, and the distribution of gainsharing amounts or other payments that may comply with the federal waiver may still violate a state's anti-kickback statute. For example, if the distribution of gainsharing payments or shared savings to physicians serves as an inducement for the physicians to make referrals to a particular

entity, it could be found to violate state law. Thus, arrangements must be analyzed for compliance with state anti-kickback statutes regardless of whether a federal waiver has been granted.

State Self-Referral Law. Many states have their own version of the federal Stark law, prohibiting referrals by physicians for certain services to entities in which the physicians have a financial interest, unless an exception applies. It is possible that participants could create a financial relationship between a referring physician and an entity furnishing services subject to the state self-referral law, and there may be no readily available exception. Once again, a waiver of the application of the Stark law does not ensure compliance with corresponding state laws, and a separate state self-referral analysis is incumbent on the participants to any bundled payment program.

State Antitrust Laws. Likewise, many states have their own antitrust laws that are similar to federal antitrust laws. Accordingly, participants in any bundled payment program will need to be mindful of these state antitrust laws, just as they will need to be aware of the federal laws.

Health Plan or HMO laws. Many states have HMO licensure laws that could be interpreted as requiring Initiative participants to have a health plan or HMO licenses, especially under prospective bundling models like Model 4, because the Awardee provides health care services in exchange for a single, prospectively determined, payment, and put the providers at risk. Thus, applicants may wish to consider carefully their state regulatory scheme and/or obtain guidance from the applicable state regulatory agency, as they move forward with their planning, to avoid potential non-compliance.

Conclusions

The Initiative represents the latest development in CMS's ongoing efforts to promote a broader shift in the Medicare program toward a risk-based reimbursement model with an emphasis on care integration and improved quality of care. As with the proposed Medicare ACO program, CMS and the Center have set the bar for participation in the Initiative very high and under an accelerated timeline.

Hospitals that elect to participate must agree to accept a discount on existing payment rates, and the Initiative offers Awardees limited upside (*i.e.*, the difference between the target price and the bundle payment amount), and potentially unlimited downside (*i.e.*, Awardees will be at risk for 100% of expenditures in excess of the as-yet-undefined "risk threshold") – all without the ability to require patients to remain within the participating group of providers. Moreover, in order to ultimately succeed, hospitals likely will need to have already developed (or be able to quickly develop) integrated delivery systems with a creative model design, thoughtful financial model and robust information systems, organizational capacity, and quality measures. Accordingly, determining the attractiveness of participating in any of the four proposed bundling models will require providers to understand and analyze not only their own projected performance, but also the expected performance of non-participating providers who may care for patients during the post-episode monitoring period. And because the Initiative lays out only high-level economic principles, prospective applicants will need to analyze several key variables to determine whether a proposed arrangement will be economically viable, including the level of discount to offer Medicare and, under some models, which conditions to include as episode anchors and how long to make the episode. These analyses will require providers to have a deep and detailed understanding of the care processes and economics that surround their Medicare patients – and how much they can realistically hope to change or control them.

Even assuming a hospital determines that participation in the Initiative might be operationally and economically viable, prospective applicants will need to carefully address the myriad regulatory issues the Initiative raises. Given the lack of clarity surrounding how fraud and abuse waivers will work at the federal level, applications will need to be carefully structured to request waivers of federal fraud and abuse laws that specifically address the expected financial relationships under the applicant's proposal. In addition, given the host of non-waivable federal and state laws, applicants and their participating providers will need to ensure that the structure of the arrangement complies with applicable federal and state antitrust and tax laws, as well as state fraud and abuse laws.

Hospitals that successfully analyze these issues could be rewarded with an opportunity to gainshare with the Medicare program, strengthen their physician alignment through further gainsharing with their physicians, access CMS's bundled payment data and best practices, and position themselves in the bundled payment arena on the ground floor. However, as with the Medicare ACO program, regardless of whether a provider participates in the Initiative, the elements of the Initiative further underscore the probable future shape of the Medicare program. Thus, even for those who decide not to participate in the Initiative, hospitals would be well-advised to seek opportunities to deepen their organization's competencies in clinical integration, care management, and patient-centeredness in preparation for Medicare's continued shift toward risk-based reimbursement.