



**BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE
FREQUENTLY ASKED QUESTIONS**

August 23, 2011

Last Updated on January 4, 2012

Because of the unprecedented public response to this initiative, CMS will need additional preparation time to accommodate the extraordinary degree of provider interest. We are therefore announcing:

Applications for the Bundled Payments for Care Improvement Models 2-4 are now due on April 30, 2012.

OVERVIEW

What is the Bundled Payments for Care Improvement initiative? (August 23, 2011)

The Bundled Payments for Care Improvement initiative is a new Affordable Care Act initiative launched by the Innovation Center designed to encourage doctors, hospitals and other health care providers to work together to better coordinate care for patients both when they are in the hospital and after they are discharged. This initiative intends to:

- a. Support and encourage providers who are interested in continuously reengineering care to achieve “better health, better care, and lower costs through continuous improvement” (three-part aim outcomes).
- b. Create a positively reinforcing cycle that leads to decreasing the cost of an acute episode of care and the associated post-acute care while fostering quality improvement.
- c. Develop and test payment models that create extended accountability for three-part aim outcomes for acute and post-acute medical care.
- d. Shorten the cycle time for adoption of evidence-based care.
- e. Create environments that stimulate rapid development of new evidence-based knowledge.

How does the Bundled Payments for Care Improvement initiative interact with the *National Pilot Program on Payment Bundling* as required in section 3023 of the Affordable Care Act (section 1866D of the Social Security Act)? (August 23, 2011)

CMS may be implementing the National Pilot Program required by the Affordable Care Act to be in place by January 1, 2013 at a later date. The Bundled Payments for Care Improvement initiative is a separate initiative being undertaken under the Innovation Center’s authority. It is designed to provide opportunities for care improvement that are consistent with the goals and approach of the National Pilot Program on Payment Bundling authorized by the Affordable Care Act. The Innovation Center is committed to being a trustworthy partner in promoting opportunities for all health care providers to improve the quality of care while reducing costs through continuous improvement. The Bundled Payment for Care Improvement initiative will help inform future Innovation Center and Department of Health and Human Services

activities that aim to improve the quality of care for Americans.

What are Bundled Payments? (August 23, 2011)

There are a number of contexts in which Medicare uses the term “bundled payment” but it generally means that rather than paying separately for each item or service, a single payment is made for a defined group of services. The bundled payment may cover services furnished by a single entity (hospital or other provider) or it may be used to pay for items and services furnished by several providers in multiple care delivery settings.

The bundled payment may cover services furnished by a single entity (hospital or other provider). In this context, bundled payment refers to a single negotiated episode payment of a predetermined amount for all services (physician, hospital, and other provider services) furnished during an episode of care. This could be paid prospectively or retrospectively. For example, Medicare and the awardee would agree to a bundled payment target price for acute care hospital services for an inpatient stay plus professional services and post-acute care related to the principal reason for the hospitalization, rather than paying separately for each physician visit and procedure provided during the episode.

How do bundled payments differ from capitation payments, such as those made to health plans under the Medicare Advantage program? (August 23, 2011)

Bundled payments differ from capitation or global payments in that the bundled payment is a single payment amount for services related to a clinical condition in a specified episode only, rather than for all care for a patient during a specified time period. For example, services for a traumatic injury occurring within the episode time window may not be included in the bundled payment amount and could be paid separately.

BENEFICIARY CHOICE

How will CMS ensure that Medicare beneficiary choice and quality is preserved? (August 23, 2011)

Nothing in this initiative limits in any way a Medicare beneficiary’s right to receive care from the health care provider of their own choosing. Medicare beneficiaries have the right to choose a different Medicare provider for their care who is not part of the Bundled Payments for Care Improvement initiative. Applicants will, in part, be evaluated based on their proposed plans to provide beneficiaries with information about the applicant’s participation in this initiative, as well as proposed plans for beneficiary engagement and inclusion in redesigning care. Medicare will require all providers applying to the Bundled Payments for Care Improvement initiative to include a strict quality monitoring program as part of the application. Quality measures, internal monitoring, and quality improvement protocols will be required.

I am a Medicare beneficiary, how will I be affected if my health care provider is participating in the Bundled Payment for Care Improvement initiative? (August 23, 2011)

As with all CMS pilot initiatives that test new models of care delivery and Medicare payment, beneficiary protection is a top priority of the initiative. As part of the application process, applicants must detail how they intend to notify Medicare beneficiaries of their involvement in the Bundled Payments for Care Improvement initiative and explain the potential implications of the initiative for the beneficiary’s care. When a provider participates in this initiative, the initiative includes all Medicare beneficiaries who receive care from that provider and who meet the episode definition. Applicants must commit to providing quality of care at or above the quality of care that all Medicare beneficiaries currently experience. CMS will rigorously monitor all participating providers to ensure that the quality of care is at least the same as, if not better than, it was prior to the initiative, and CMS may terminate provider participation in the initiative

if the quality of care decreases or there are other significant beneficiary concerns. As always, Medicare beneficiaries have the right to choose a different Medicare provider for their care who is not part of the Bundled Payments for Care Improvement initiative.

THE BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE

How will Medicare pay awardees and participating providers? (September 9, 2011)

In Model 1, Medicare will continue to pay acute care hospitals under the Inpatient Prospective Payment System (IPPS). However, these payments to participating acute care hospitals will be at a reduced payment amount that reflects the applicable discount percentage on all MS-DRGs that is reflected in the awardee's provider agreement. Medicare Part B payments to physicians and other practitioners will not change. Discounted IPPS payments for all MS-DRGs will be made to any participating acute care hospital where a beneficiary receives treatment, including a hospital participating as a partner with an awardee convener or with another awardee. The awardee is responsible for some financial risk if aggregate Medicare Part A and Part B expenditures increase beyond a risk threshold for the period of the inpatient stay or during the 30 days after discharge, compared to historical expenditures.

In Models 2 and 3, Medicare payments will not change; Medicare will continue to pay each provider under the current applicable fee-for-service payment system at the applicable amounts for the dates of service. After the episode of care concludes, the aggregate Medicare expenditures for the episode of care will be compared to the target price. If the actual expenditures were less than the target price, Medicare will pay the difference to the awardee. If the actual expenditures were more than the target price, the awardee will pay the difference to Medicare.

In Model 4, Medicare will make a single, prospectively established bundled payment to the acute care hospital where a beneficiary is hospitalized. All Part A and Part B physicians' services furnished during the inpatient stay are included in the bundled payment, and the hospital would be responsible for distributing the payment to the other providers caring for the patient. If the admitting hospital is not the awardee, the awardee would not receive payment from Medicare for the episode. The awardee (whether or not the admitting hospital) would be financially responsible for Medicare expenditures for any related readmissions during the readmission window, as well as for increases in aggregate Medicare Part A and Part B expenditures beyond a risk threshold during the 30 days after discharge compared to historical expenditures.

Does Model 1 include all MS-DRGs? Will applicants be able to propose a subset of MS-DRGs to include? (September 9, 2011)

In Model 1, applicants will propose a single rate of discount that will apply to Part A payments for inpatient hospital services for all MS-DRGs. Applicants cannot propose a subset of MS-DRGs to include in the initiative under this model. The discount can be phased in from no minimum discount for the first six months, increasing to a 2% minimum in the third year. However, Model 1 awardees that also participate in another model under this initiative will have the MS-DRGs identified for those other models removed from the Model 1 payment changes.

How does Model 4 of this initiative differ from the Acute Care Episode (ACE) demonstration? (September 9, 2011)

Model 4 of the Bundled Payments for Care Improvement initiative is very similar to the ACE Demonstration. Both pay prospectively-established bundled payments for inpatient hospital and physicians' professional services furnished during an acute care hospitalization. Model 4 includes readmissions related to the initial hospitalization within a minimum of 30 days after discharge, while the ACE demonstration does not (except readmissions on the day of discharge). Unlike the ACE

Demonstration, Model 4 will not include a beneficiary shared savings component. In the ACE demonstration, the discount to the MS-DRG payment that is the basis for the prospectively established bundled payment amount included outlier and capital payments, but excluded indirect medical education (IME) and Disproportionate Share Hospital (DSH) payments. In contrast, in Model 4 of this initiative, the discount to the MS-DRG payment that is the basis for the prospectively established bundled payment amount will include outlier payments but exclude capital, IME, and DSH payments. The Bundled Payments for Care Improvement initiative expands upon the ACE Demonstration by including more conditions (more MS-DRGs) and does not limit the demonstration to certain geographic regions.

What methodology will CMS use to trend forward target prices? (September 9, 2011)

CMS's methodology for trending forward target prices will be determined after applications are received and prior to awards being made. Please use data from calendar year 2009 for your historical payments, and propose a target price in calendar year 2009 dollars. CMS will trend proposed target prices to calendar year 2012 dollars for purposes of final agreements with awardees. The target price will be further trended forward in subsequent years of the performance period.

What impact will the Bundled Payments discounts have on indirect medical education (IME), disproportionate share hospital (DSH), and outlier payments? (September 20, 2011)

Discounts to MS-DRG payments under this initiative will not be applied to IME or DSH payments, therefore those payments will not change. The calculation of these additional payments for each specific model is described below.

In Model 1, IME, DSH, and outlier payments will be calculated using the non-discounted base payment amount and then paid, if applicable, in addition to the discounted MS-DRG operating payment.

In Models 2 and 3, all Medicare fee-for-service payments will be paid at the usual rates. When determining the target price, applicants should include outlier payments in their calculations; outlier payments will be included in the episode reconciliation calculation when determining whether the awardee has met the target price. The target price will exclude IME and DSH payments, and the payment reconciliation calculation will exclude IME and DSH payments from the index admission (Model 2) and readmissions (Models 2 and 3) when calculating the actual expenditures for comparison with the target price.

In Model 4, IME and DSH payments will be calculated based on the non-discounted base operating payment that would otherwise be paid for the applicable MS-DRG for the episode. IME and DSH payments will be paid in addition to the bundled episode payment, which does not include IME and DSH payments. In determining the bundled payment for the episode, outlier payments will be included in the price calculation. Therefore there will be no additional outlier payments.

My Model 2, 3, or 4 episode definition includes multiple MS-DRGs for the same clinical condition. Should I propose one target price or bundled payment amount that applies to all of the included MS-DRGs, or should I propose a separate target price or bundled payment amount for each MS-DRG? (September 20, 2011)

In Models 2, 3, and 4, applicants will propose an episode definition, which should include the MS-DRGs targeted, the length of the episode (Models 2 and 3) or length of the readmission window (Model 4), and related services. We encourage applicants to include multiple MS-DRGs in their episode definition, and

particularly encourage applicants to propose episode definitions that include all of the MS-DRGs for the relevant clinical conditions that reflect the various complications and comorbidities that may apply to Medicare beneficiaries.

Proposed episode definitions that include multiple MS-DRGs should use the same rate of discount across all DRGs in that episode definition. For example, if your episode includes four MS-DRGs, you should apply the same rate of discount to each 2009 average cost per episode to determine your proposed target prices or bundled payments amount for the episode. Or, for example, your episode may include three MS-DRGs for the same condition for a diagnosis without complications and/or comorbidities, one with complications and/or comorbidities, and one with major complications and/or comorbidities. In this case, you should complete a separate application Table C 1 for each MS-DRG, using the same episode definition (i.e., the same time parameters and services included), and applying the same rate of discount to each 2009 average cost per episode to determine your proposed target prices or bundled payment amounts.

Can a beneficiary who is transferred to or from a participating acute inpatient facility be included?
(January 5, 2012)

Yes. If an eligible beneficiary is admitted to a participating provider and then transferred to another acute inpatient hospital, he or she is included in the program if the admission at the participating provider is for an assigned MS-DRG (or any MS-DRG for Model 1). If an eligible beneficiary is admitted to a non-participating acute inpatient hospital and transferred to a participating provider, he or she is included in the program if the admission at the participating provider is for an assigned MS-DRG (or any MS-DRG for Model 1). In Model 1, the discount will be applied to the participating provider's IPPS payment. In Model 2 and Model 4, the episode of care will begin at admission to the participating provider if the admission is for an assigned MS-DRG.

If my application includes a proposal for gainsharing, must I seek a waiver from the OIG?
(September 9, 2011)

Under Section 1115A(d)(1) of Title XI of the Social Security Act, as added by Section 3021 of the Affordable Care Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII, as well as Sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), as may be necessary for purposes of carrying out Section 1115A with respect to testing of models described in section 1115A(b). The Secretary will consider exercising this waiver authority with respect to the fraud and abuse laws in Titles XI and XVIII as may be necessary to develop and implement the Bundled Payments for Care Improvement initiative. The Secretary may also consider waiving additional provisions under Title XVIII for this purpose. We anticipate that applicable waivers, if granted, would be included in the terms and conditions of the agreement between CMS and the awardee(s) and/or providers.

Are participants in the Bundled Payments for Care Improvement initiative prohibited from engaging in gainsharing arrangements that involve items or services furnished to individuals whose care is paid for by a commercial payor? (October 20, 2011)

Participants in the Bundled Payments for Care Improvement initiative are not prohibited by the terms of the program from engaging in gainsharing arrangements involving care furnished to private pay patients. Such arrangements may implicate federal fraud and abuse laws, as well as state and local laws.

Accordingly, participants in this initiative must ensure that private pay gainsharing arrangements comply with any applicable federal, state and local laws, or the terms of any applicable waiver of those laws. We anticipate that the terms of any such waiver of the federal fraud and abuse laws would protect a gainsharing arrangement pursuant to which participants in this initiative rendered services to Medicare beneficiaries.

I am a physician. If I am participating in an approved gainsharing arrangement through this initiative at one participating hospital, may I also participate in another approved gainsharing arrangement with another participating hospital? (October 20, 2011)

Yes, physicians are welcome to participate in multiple approved gainsharing arrangements through this initiative.

I would like to waive Medicare coinsurance/copayments/deductibles for beneficiaries included in this initiative. May I apply for a waiver to do so through this initiative? (October 20, 2011)

Under Section 1115A(d)(1) of Title XI of the Social Security Act, as added by Section 3021 of the Affordable Care Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII, as well as Sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii), as may be necessary for purposes of carrying out Section 1115A with respect to testing of models described in section 1115A(b). The Secretary will consider exercising this waiver authority with respect to the fraud and abuse laws in Titles XI and XVIII as may be necessary to develop and implement the Bundled Payments for Care Improvement initiative. The Secretary may also consider waiving additional provisions under Title XVIII for this purpose. Applicants may propose such waivers in their application and should provide a compelling explanation for why such waivers are necessary to their model design.

BUNDLED PAYMENTS AND MEDICAID

How does this initiative affect beneficiaries enrolled in both Medicare and Medicaid (often called “dual eligibles”)? How does this initiative affect Medicaid providers? (September 20, 2011)

The Bundled Payments for Care Improvement initiative will be targeted to all Medicare FFS beneficiaries with Part A and Part B coverage. Dual eligibles, are not excluded from receiving care under the demonstration unless they would otherwise not be able to participate (e.g. because they are a Medicare Advantage enrollee or because they have end-stage renal disease). If a dual eligible beneficiary receives Medicare-covered care for an included condition from a participating provider, the episode of care will be included in the initiative.

While the current bundled payments demonstration and payment methodology are based upon Medicare spending, for Medicare-Medicaid enrollees CMS encourages providers to engage with States, particularly in better coordinating care for Medicare-Medicaid enrollees. And CMS will look favorably on applications that demonstrate partnership with State Medicaid programs. CMS is also interested in and plans to monitor the impact of the initiative on Medicaid expenditures with respect to dual eligibles.

Is CMS planning a state-oriented Medicaid bundled payment initiative? (September 20, 2011)

The Bundled Payments for Care Improvement initiative will test alternative models for payment in Medicare fee-for-service (FFS) to incentivize care redesign, engage and protect beneficiaries, and learn and diffuse best practices in order to inform potential changes to the Medicare FFS program. CMS will look favorably on applications that demonstrate partnership with State Medicaid programs, private payers, or multi-payer collaboratives to redesign care. Medicaid providers may be able to participate if their State Medicaid program partners with providers in this initiative. States can also apply as conveners in this current opportunity. Furthermore, State Medicaid programs may be able to pursue various payment reform initiatives, including bundling, through State plan and waiver authority.

POTENTIAL APPLICANTS

Who should apply for the Bundled Payment for Care Improvement initiative? (August 23, 2011)

This initiative seeks innovative proposals that will build on the success of previous CMS demonstrations and private sector initiatives. In all models contained in this Request for Applications (RFA), CMS is seeking proposals that:

- affect broad categories of conditions;
- reach many beneficiaries;
- offer significant savings to Medicare;
- are designed to be scalable and replicable by similar health systems around the country; and
- are able to be implemented on aggressive timelines.

Applicants are anticipated to have experience with cross-provider care improvement efforts of this type, and either have already begun to redesign care or are prepared to redesign care and enter into payment arrangements that include financial and performance accountability for episodes of care. For more information related to applicant selection criteria, please refer to the RFA.

Can I apply and/or participate in multiple models? (August 23, 2011)

Yes. Applicants are welcome and encouraged to apply for and participate in one or more models. Letters of Intent (LOI) must be submitted separately for Model 1 and for Models 2-4; however, applicants interested in applying for more than one of Models 2-4 can submit one LOI for these models. Applicants must submit a separate application for each proposed model. The LOI and application for Model 1 are due by September 22, 2011 and October 21, 2011, respectively; the LOI and application for Models 2-4 are due by November 4, 2011 and March 15, 2012, respectively. These applications will be considered separately. Please refer to the "Application Submission, Review Process and Selection Criteria" section of the RFA, as well as the applications, for further details on additional information applicants must provide if applying for multiple models.

If a Model 1 awardee applies for and is selected for Models 2 or 4 that include episode payment for certain MS-DRGs, CMS will amend the Model 1 agreement to exclude those MS-DRGs for patient episodes from Model 1. This will ensure that the same clinical cases are subject to only a single episode payment model.

What kinds of applicants is CMS seeking for this initiative? (August 23, 2011)

CMS is seeking to partner with providers who are committed to using bundled payments as a tool towards redesigning care to achieve three-part aim outcomes. Specifically, CMS is seeking proposals that affect broad categories of conditions, reach many beneficiaries, offer significant savings to Medicare in the context of a robust programmatic design; are designed to be scalable and replicable; involve participation by other payers; and are able to be implemented on aggressive timelines. Additionally, for all models, CMS will give preference to applicants who are meaningful users of health information technology or who have a minimum of 50% of their providers meeting the standards for meaningful use. For Models 2 and 3, CMS will give preference to applicants proposing an episode definition longer than 30 days. CMS will also look favorably on applications that indicate a higher historical rate of physician participation in the Physician Quality Reporting System (PQRS) as well as describe plans to encourage greater physician participation in PQRS for the duration of the initiative. Finally, CMS will view favorably applications that include governing bodies with meaningful representation from consumer advocates, patients, and all participating provider types/organizations, and applications that include functional status in the proposed quality measures. For a more detailed list of application review criteria, please refer to the "Application and Selection Process" section of the RFA.

Will CMS limit the number of awardees for a particular condition or in a health care market?
(September 9, 2011)

CMS will not limit awardees based on geographic region, geographic type (e.g., urban, rural), or size of health system. CMS will prioritize applications based on scores on the criteria listed in the Request for Applications (RFA) and on other considerations described in the RFA. CMS is interested in selecting awardees that will allow the evaluation of the initiative to best inform our recommendations regarding rapid replication and scaling; this interest will inform awardee selection and could result in selection of a number of awardees for a particular clinical condition or in a particular health care market. However, we look forward to having a broad geographic distribution of awardees in the initiative.

I am part of, or represent, an organization that would like to apply to be an Accountable Care Organization (ACO). Can I apply for the Bundled Payments for Care Improvement initiative?
(August 23, 2011)

Yes. We know that healthcare transformation requires some synergy between new payment methods and care improvement strategies. The Bundled Payments for Care Improvement initiative is not a shared savings program with Medicare, so CMS encourages entities to participate in the Bundled Payments for Care Improvement initiative and the Medicare Shared Savings Program, the testing of the Pioneer ACO Model, medical home initiatives, and other shared savings initiatives. However, each application will be reviewed in light of the programs the applicant is participating in and the applicant's individual circumstances. However, CMS reserves the right to potentially subject these entities to additional requirements, modify program parameters, or ultimately exclude participation in multiple programs, based on a number of factors, including the capacity to avoid counting savings twice in interacting programs and to conduct a valid evaluation of the proposed interventions.

My hospital is a psychiatric hospital/critical access hospital. Can my hospital participate?
(Updated October 25, 2011)

To be eligible to apply as an awardee, a hospital's payment for treating Medicare fee-for-service beneficiaries must be made fully and solely under the Inpatient Prospective Payment System (IPPS). Hospitals paid under the Inpatient Psychiatric Facility Prospective Payment System (IPF PPS), paid on a cost basis, or paid under the IPPS but supplemented by another methodology are not eligible to be the awardee. These providers are welcome to participate in the initiative as partners with other eligible awardees to redesign and improve care, and they may also share in any gains that result from improved care if the hospital agrees to share the gains they receive.

Are sole-community hospitals eligible to apply as awardees for the Bundled Payments for Care Improvement initiative? (October 25, 2011)

Sole community hospitals are paid under the IPPS, and thus they are eligible to apply as awardees for the Bundled Payments for Care Improvement initiative. We apologize for any misleading or inconsistent messages that have been circulated regarding the eligibility of sole community hospitals, and we can confirm at this time that we will accept applications from sole community hospitals for this initiative.

I am a Home Health Agency (HHA)/Inpatient Rehabilitation Facility (IRF)/Skilled Nursing Facility (SNF)/Long-Term Care Hospital (LTCH). How can I participate in this initiative? (September 9, 2011)

HHAs, IRFs, SNFs, and LTCHs can participate in the Bundled Payments for Care Improvement initiative in a number of ways. Models 2 and 3 include the post-acute care following an acute care hospital stay. These post-acute providers are eligible to apply to be the awardee for Model 2 or Model 3. In Model 2,

the episode of care includes the acute care hospital stay and all Part A and Part B services related to the targeted condition for the duration of the episode, which begins at acute care hospital admission and ends a minimum of 30 days after hospital discharge. In Model 3, the episode of care includes all Part A and Part B services related to the targeted condition for the duration of the episode. The Model 3 episode begins when a beneficiary who was discharged from an acute care hospital stay for the targeted condition initiates post-acute care services with a participating IRF, SNF, LTCH, or HHA within 30 days of hospital discharge, and the episode lasts a minimum of 30 days.

In Models 2 and 3, Medicare payments will not change; Medicare will continue to pay each provider under the current applicable fee-for-service payment system at the applicable amounts for the dates of service. After the episode of care concludes, the aggregate Medicare expenditures for the episode of care will be compared to the target price. If the actual expenditures were less than the target price, Medicare will pay the difference to the awardee. If the actual expenditures were more than the target price, the awardee will pay the difference to Medicare.

HHAs, IRFs, SNFs, and LTCHs can also participate in Models 1 and 4 of this initiative, though the episodes of care included in these models do not include post-acute care. If post-acute providers choose to partner with participating hospitals and physicians to redesign care under Model 1 or Model 4, they can share in any resulting gains if the hospital agrees to share the gains they receive.

I am a multi-campus hospital with one CMS Certification Number (CCN) for all sites. Can I apply for only one site within my hospital to participate? (October 20, 2011)

If a provider applies to participate, all providers sharing that same CCN must also participate. If a multi-campus hospital with one CCN covering all sites applies, all sites covered by that CCN must participate, and must participate with the same parameters (such as the same discount rate, and for Models 2-4, the same episode definition).

I am a multi-campus hospital, hospital system, or convener whose participating hospitals each have their own CCN. Can multiple sites participate with different episode definitions and/or discount rates? (October 20, 2011)

If a hospital system or convener of multiple hospitals applies (as either an awardee convener or a facilitator convener) each hospital within that system or network may propose different parameters (i.e. (i.e. Model definition, discount rate, gain sharing methodology, etc.) provided each hospital has a different CCN, and a strong rationale is presented in the application to justify the necessity of different parameters. Applications from conveners that foster the participation of large numbers of providers, affecting large numbers of beneficiaries in a consistent, organized, and efficient manner, may be considered favorably. If multiple providers are applying under one convener, while the parameters are permitted to vary by provider, we would anticipate that the general approach would be substantially consistent across all participating providers. We would expect the convener's application to present compelling reasons for variations in methodology among different providers applying together under a single convener, because otherwise these providers could each apply separately for the program.

I am a physician group practice applying as an awardee or awardee convener for Models 2 or 3. The Request for Applications (RFA) states that all beneficiaries eligible for the episode (based on MS-DRG) must be included in the bundled payment model. What does this mean for my organization? (October 20, 2011)

CMS welcomes applications from physician groups. For physician groups applying as an awardee or an awardee convener, all beneficiaries with an included MS-DRG treated by any physician in the awardee physician group, regardless of the hospital or post-acute provider at which the beneficiary is treated, must be included in the bundled payment model. Under a scenario where all Medicare beneficiaries in a given MS-DRG in a hospital or treated by a post-acute care provider after a hospitalization for the MS-DRG may not be included in the episode, applicants should provide additional information to address the potential for shifting of patients outside the episode by changing the treating physician to one who is not a member of the awardee physician group. This should include information such as how patients are assigned to physicians in the hospitals and post-acute provider settings; referral patterns and anticipated changes to these referral practices as a result of this initiative; percentage of cases that meet the episode definition and that were under the care of members of this physician group at each hospital and/or post-acute provider for at least the past three years; as well as any additional information the applicant believes is necessary to describe how this concern about changes in case mix related to the episode incentives could be ameliorated. In addition, because CMS views episode payments as a payment lever to achieve three-part aim care episode redesign outcomes, physician group applicants should describe fully their plans to redesign care in all of the relevant settings (i.e., hospital and post-acute care providers) caring for beneficiaries in the episode. This could include information on the physician group's partnership with the relevant facility (i.e., hospital), data on the percentage of physicians with privileges at a given hospital and/or post-acute care provider who are members of this physician group, as well as other information describing how the physician group's redesign efforts will reduce episode costs (including institutional costs) through redesign.

Physician group practices applying as an awardee may attach an additional 10 pages of appendices to the application to address these issues. Applicants applying as a convener are already permitted an additional 10 pages per site; these questions should be answered within that page limit.

DATA REQUESTS

I am an interested applicant, but I don't have enough data to decide how to define the various episodes of care and subsequently come up with a target price or prospective bundled payment amount. What can I do to get the information I need? (August 23, 2011)

CMS will provide historical Medicare claims data to potential applicants submitting letters of intent for Models 2–4. The data are intended to enable potential applicants to develop robust episode definitions and target prices or prospective bundled payment rates based on the historical experience of providers in the applicant's geographic area. To be eligible for receipt of data, applicants must develop a research request packet to be approved by CMS. Applicants must also sign and comply with a data use agreement and conform to all applicable privacy laws. For more information please refer to the "Application Submission Process" section of the RFA, or <http://www.innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html> or email BundledPayments@cms.hhs.gov.

Will the Limited Data Set (LDS) files that CMS will provide to prospective applicants who wish to conduct research into possible structures for bundled payment models and episodes of care include the same data elements as the LDSs that are typically provided when researchers request LDS files? Do they contain the same fields, and will they cost the same amount? (September 20, 2011)

The standard files that will be made available to potential applicants who wish to conduct bundled payment model and episode of care research will contain typical LDS fields. The data will include beneficiary-level claims with masked beneficiary identifiers. Specifically, the Limited Data Set will cover the potential applicant's geographic region and will include at a minimum Part A and Part B payment

amount, MS-DRG/HCPCS codes (as applicable), services rendered, dates of services, diagnosis and procedure codes, and institutional provider, as well as beneficiary age and sex.

Furthermore, we find that charging for the data that is needed to conduct research into possible structures for bundled payment models and episodes of care may severely limit the number of potential applicants in a manner that would be detrimental to the success of the Bundled Payments for Care Improvement initiative. We have therefore elected to invoke the Innovation Center's authority to waive "such requirements of titles XI and XVIII [of the Social Security Act (SSA)] as may be necessary" (section 1115A(d)(1) of the SSA) to carry out the program. We will waive data fees for potential applicants to this initiative who submit a data request for purposes of conducting bundled payment model and episode of care research in preparation for applying to the program.

What degree of detail will be available through the limited datasets that are being provided to prospective applicants who wish to conduct research into possible structures for bundled payment models and episodes of care? Will it include the complete set of services? (September 20, 2011)

The LDS files that will be provided to prospective applicants to this program who successfully complete the Research Request Packet submission process will include beneficiary demographic information, as well as inpatient hospital, outpatient hospital, home health agency, skilled nursing facility, durable medical equipment, and carrier files. No hospice or Part D files will be available through the bundled payment models and episodes of care Research Request Packet submission process.

Can I share the data I receive with my partner institutions? (September 20, 2011)

The use of the data that is requested and received through this program is governed by the data disclosure conditions described in the Research Request Packet and the use and disclosure limitations in the Data Use Agreement. Data will not be transmitted to prospective applicants who wish to conduct research into possible structures for bundled payment models and episodes of care until the potential researcher has executed a data use agreement in which they agree to abide by the use and disclosure limitations. Among other requirements, the DUA will require that any person or entity that the recipient subsequently discloses the data to will sign a DUA signature addendum in which they agree to the same terms and conditions on use and disclosure as the original recipient. The DUA from the original requestor, along with any relevant signature addenda, must be submitted to and accepted by CMS before data will be released to any potential applicants. If any additional individuals access, receive or use the data provided without having signed the DUA or DUA signature addendum, the original recipient will be found in violation of the DUA. The DUA only covers use and disclosure of CMS data. You may share the outcome of your analysis with your Bundled Payment partner organizations if those analyses are stripped of CMS' data. Your partners will be able to use those CMS data-stripped findings to complete the application without having to sign a DUA signature addenda.

I am interested in receiving CMS data but I am not applying to the Bundled Payments for Care Improvement initiative. How do I get access to this data for this purpose? (October 25, 2011)

The Bundled Payments for Care Improvement team recognizes the importance of research into structures for bundled payment models and episodes of care outside the parameters of the Bundled Payments for Care Improvement initiative; however, at this time it is not possible to apply for data through the process outlined in the Research Request Packet and Data Use Agreement (DUA) on the Bundled Payments for Care Improvement website unless you are planning to apply for the initiative. If you are not planning to

applying for the initiative, you are welcome to apply for research data through the Research Data Assistance Center using the method described on their website: http://www.resdac.org/Medicare/requesting_data.asp. This request will be processed through the normal channels, distinct and separate from those channels created specifically for potential applicants to the Bundled Payments for Care Improvement initiative.

I am applying to the initiative and would prefer to reuse CMS data that I already have access to from prior research instead of applying for a dataset through the process described on the Bundled Payments website. How do I gain permission to reuse data for this purpose? (October 25, 2011)

If you have already received Medicare data for another research purpose and would like to reuse it to examine structures for bundled payment models and episodes of care in preparation for an application to the Bundled Payments for Care Improvement initiative, you may apply for an amendment to your existing DUA using the process outlined on the website of the Research Data Assistance Center, as follows: http://www.resdac.org/Medicare/requesting_data.asp. This request will be processed through the normal channels, distinct and separate from those channels created specifically for potential applicants to the Bundled Payments for Care Improvement initiative.

I am applying as a convener, and I would like to request data for all of my participating institutions. How do I fill out the Research Request Packet and Data Use Agreement? Does every participating organization need to sign these forms? (October 25, 2011)

If you are applying as a convener and are planning to do centralized data analysis in a standardized fashion for all of your participating organizations, your organization may apply for data with one Research Request Packet and DUA, and without signatures from each of your participating organizations. Please note that we expect the submission of a request for research data on behalf of another organization partnering in your potential application signals awareness of that submission by all parties, and to this end we will be corresponding with all institutions listed on a convener's data application to notify them that data has been requested by the convener in regard to the institution's participation in a potential application by that convener. Please also note that the use of data that is requested and received through this program is governed by the data disclosure conditions described in the Research Request Packet and the use and disclosure limitations in the DUA. If any additional individuals access, receive, or use the data provided without having signed the DUA or DUA signature addendum, the original recipient of data will be found in violation of the DUA.

I am applying for the program and would like a third party to do data analysis on my behalf. Does that entity need to appear in my Research Request Packet and Data Use Agreement? If so, how? (October 25, 2011)

If an entity other than an applicant is planning on conducting data analysis on behalf of that applicant, that entity should appear on the DUA as the custodian of the data, and as the primary user if they are planning to act as such. The applicant organization should fill out the Research Request Packet and DUA, but the custodian will need to either fill out or provide to the applicant information to complete any fields that require responses specific to the custodian, such as the list of key personnel, shipping and contact information, and any data management information necessary. Please note that it is possible to designate the custodian as the party to receive the data, if desired. Both parties, the applicant and the custodian, must appear on both documents and both must sign the DUA. Please also note that the use of data that is requested and received through this program is governed by the data disclosure conditions described in the Research Request Packet and the use and disclosure limitations in the DUA. If any additional individuals access, receive, or use the data provided without having signed the DUA or DUA signature addendum, the original recipient of data will be found in violation of the DUA.

Do I need to fill out Attachment A on the Data Use Agreement? (October 25, 2011)

No, you do not need to fill out Attachment A on the Data Use Agreement. This information is contained within the Research Request Packet.

If I request historical Medicare claims data for Models 2, 3 or 4 by submitting a Research Request Packet, when will I receive the data? If I submit the research request packet prior to the November 4, 2011 deadline, will I receive the data earlier? (September 9, 2011)

We anticipate that all applicants who request data will receive it at approximately the same time, so as to allow all applicants an equal amount of time to prepare their applications. Therefore, submitting the Research Request Packet prior to November 4, 2011 will not expedite receipt of data. We anticipate that all applicants who request data will have approximately two months between receipt of the data and the application deadline.

What are the data specifications of the data I will receive if my Research Request Packet and Data Use Agreement are approved? What does it mean when you say that data extracts will be delivered in CSV format with a SAS program? (October 25, 2011)

The data files will have a .dat extension. They are fixed column ASCII format files. CMS will provide the SAS read-in programs as well as File Transfer Summary (FTS) documents. If you are not using SAS to analyze your data, the FTS document will serve as a layout.

We anticipate more detailed information regarding the data, including a variable listing, will be posted on our website in late November 2011.

The RFA mentions “CY2008 summary data for 18 sample episode definitions that include combinations of acute and post-acute care.” Is this extra data that is separate from the LDS files, and how will I access it? Do I need to submit a research request packet to get this information? (September 20, 2011)

The 18 sample episode definitions and summary data supporting them will be made available separately from the LDS files. You do not need to submit a research request packet to have access to the summary data. More information on how to access these data will be available on the Bundled Payments for Care Improvement website by early November.

I requested data as a potential applicant to one or more of Models 2-4, but I have been notified that I did not receive all of the Hospital Referral Clusters (HRCs) that I requested in my Research Request Packet. Why won't I receive all the HRCs that I requested in order to assist in preparing my application for the Bundled Payments for Care Improvement initiative? (January 5, 2012)

Any data requestor who asked for more than one Hospital Referral Cluster was required to specify the percent of their patient population that resides in each cluster (or, in the case of conveners requesting more than one region of data for any one partner institution, the percentage of the patient population that resides in each cluster for each partner institution). In our analysis of these requests, we ensured that every data requestor was able to receive enough data to cover at least 85% of their patient population. For data requestors who specified the HRC of residence for at least 85% of their patient population, enough HRCs were approved to cover at least 85% of their patient population. We selected these approved HRCs from the complete list of requested HRCs in priority order, starting with HRCs that contained the largest percentage of your patient population and continuing in order until at least 85% of the patient population had been covered. **All entities who requested data should receive either a**

notification of their approved HRCs or an explanation of what documents are still necessary to complete their data request by 1/10/2012. If you have not been contacted regarding your approved HRCs, please do not contact CMS until after 1/10/2012 as we are currently working to get these notifications to you.

Due to the established policies governing the release of data for research that require us to provide only the minimum data necessary for the task of researching possible structures for bundled payment models and episodes of care, we were not able to provide some requestors with all the HRCs that they requested. We have done our best to ensure that all requestors have data available to them that covers at least 85% of their patient population (or, in the case of conveners requesting more than one region of data for any one partner institution, 85% of the patient population that resides in each cluster for each partner institution).

I submitted a non-binding Letter of Intent (LOI) for Models 2-4 and requested data through a Research Request Packet and Data Use Agreement (DUA). Now, I wish to add additional participating providers from other geographic regions to my application. May I request additional Hospital Referral Clusters so as to analyze data for these new partners? (January 5, 2012)

While additional providers (such as hospitals, post-acute care providers, or physicians) may join the project prior to the submission of the application on March 15, 2012, it will not be possible to submit requests for additional data covering these providers. The deadline for data requests was on November 4, 2011. You are able to add additional provider partners prior to submitting your application, but you are not able to receive data for these potential additional partners.

I work for a hospital that submitted a non-binding Letter of Intent for Models 2-4 and requested data through a Research Request Packet and Data Use Agreement. Now, I wish to add additional participating providers. These additional providers are in the same Hospital Referral Cluster as my hospital. May I analyze the data (which I have already requested) for my own hospital as well as for my new provider partners? (January 5, 2012)

If you would like to analyze data for provider partners that you have added since submitting your Letter of Intent (LOI), you must expressly request that these additional partners be added to your LOI. In order to make this request, you will need to submit the following items to BundledPayments@cms.hhs.gov. Please submit these items in a single, unencrypted email with "Additional Partners for [hospital name] LOI" in the subject line between **1/10/2012 and 1/24/2012**:

- An updated LOI that includes all provider partners (both the original partners and any additional partners that have been added). Be sure to include both CMS Certification Numbers (CCNs), if applicable, and contact information for each partner.
- A letter of consent for each partner that did not appear on your original LOI submission. This letter must identify your organization (the organization requesting the data and originally submitting the LOI) by name, and must indicate approval on behalf of the new partner to be part of the combined data analysis towards application for the Bundled Payments for Care Improvement initiative. The letter of consent must be signed by the President/CEO/Executive Director of the new organization.

Note that **this situation only applies** if the additional partners are located in Hospital Referral Clusters (HRCs) that you have already requested and been approved to receive. You cannot receive additional HRCs based on your new provider partners, and the HRCs you have been approved to receive will not be adjusted based on these additional partners (even if they change the percentage of patients residing in each HRC).

I am a convener who submitted a non-binding Letter of Intent (LOI) for Models 2-4 and requested data through a Research Request Packet and Data Use Agreement. I wish to analyze multiple HRCs of data to determine if there are hospitals or other providers who may wish to join my application. Is this permissible? (January 5, 2012)

No. The use of the data that is requested and received through this program is governed by the data disclosure conditions described in the Research Request Packet and the use and disclosure limitations in the Data Use Agreement. The data may only be analyzed on behalf of those providers who were listed on your original LOI, as submitted by November 4, 2011. While the Limited Data Set (LDS) may include services provided at other institutions, this is to allow you to analyze the care that patients receive after being discharged from the hospital or post-acute provider included on your LOI. You are not permitted to analyze the data so as to construct episodes of care for provider organizations that were not listed on your original Data Use Agreement. You are able to add additional provider partners prior to submitting your application, but you are not able to request additional data for those providers, and you are not able to analyze the data you have already requested on behalf of additional providers unless they have been expressly added to your LOI through the process laid out above..