CENTER FOR
HEALTHCARE
QUALITY &
PAYMENT REFORM

320 Ft. Duquesne Boulevard
Suite 20-J
Pittsburgh, PA 15222
Voice: (412) 803-3650
Fax: (412) 803-3651
www.CHQPR.org

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Patrick Conway, MD
Deputy Administrator for Innovation and Quality and Chief Medical Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information on Specialty Practitioner Payment Model Opportunities

Dear Patrick:

Thank you for seeking input on how CMS can support the development of innovative payment and service delivery models for outpatient care by medical specialists.

I know many physicians, from a wide range of specialties, who have innovative ideas for redesigning care delivery that could improve outcomes for patients and reduce spending for Medicare and other payers, but they are prevented from implementing these ideas by the barriers in the current payment system. Payment reforms that successfully overcome these barriers would result in significant savings for the Medicare program and significant benefits for Medicare beneficiaries. However, success will depend not only on the details of individual payment models, but whether a sufficient number of different types of payment models are made available, and how the process for soliciting participants is designed and implemented. I will offer suggestions below on how the Innovation Center could best support rapid development and implementation of successful payment reforms.

CMMI Should Accept Proposals for a Broad Range of Specialty Payment Models

The RFI suggests that you have already decided to focus only on "procedural episode-based payments" and "complex and chronic disease management episode-based payments" as the specialty payment models you will pursue. While these are certainly desirable types of specialty payment models, it would be very unfortunate if these were the only models made available, since they would only apply to a small subset of the many opportunities for improving patient care and improving costs that specialists want to pursue. For example:

- payments based solely on *procedures* would exclude the many kinds of health conditions that can be treated by specialists using medications, counseling, and other forms of non-procedural treatment. Moreover, for conditions where physicians and patients have choices of both procedural and non-procedural approaches to treatment, payment reforms limited to "procedural" episodes could unintentionally encourage the use of those

procedures vs. other types of treatment. In addition, there are many opportunities to reduce testing costs during the diagnosis and care planning process that would not be captured through episodes triggered by procedures or other forms of treatment.

- payments focused only on "complex" patients would miss the opportunity to achieve savings through more effectively managing care for the much larger population of individuals with single, early-stage chronic diseases and the individuals with the risk factors that can precede chronic disease. Although the per-patient savings from these populations may be lower than what may be possible for complex patients, the larger numbers of these patients means that total savings can still be significant. Moreover, there are not only immediate savings opportunities from better management of these populations, but also the opportunity to slow their progression to more advanced stages of chronic disease when care becomes much more expensive.

Offering a larger, but still manageable, number of alternative payment models would allow more types of specialists and more patients to participate, thereby increasing the magnitude of savings that Medicare could achieve as well as engaging a larger number of physicians in efforts to redesign care and payment. **I would recommend that you solicit proposals that would fall into in any of the following categories.**

- **Procedure-based episodes** (e.g., bundled/warranties payments for colonoscopy). This would be a single payment to a physician practice for all of the costs related to the procedure (including both the services delivered directly by the physician performing the procedure and services delivered by other physicians and facilities that are an integral part of the procedure) and also for the costs of treating complications resulting from the procedure.
- **Condition-based payment for treatment of acute conditions** (e.g., payments for treatment of illnesses or injuries that do not require hospitalization). This would be a single payment to a physician practice for all the costs related to treatment of an acute condition, regardless of which of a range of alternative treatments are used, and also the costs of treating any complications resulting from the treatments chosen.
- **Diagnostic bundles for acute conditions** (e.g., payment for diagnosis of chest pain). This would be a single payment to a physician practice for the costs of examinations and testing in order to determine an accurate diagnosis for a particular set of symptoms.
- **Condition-based payment for chronic disease** (e.g., payment for management of patients diagnosed with COPD or epilepsy). This would be a single payment to a physician practice to manage the treatment of a chronic disease and also for costs associated with exacerbations or complications of the disease.
- **Condition-specific capitation** (e.g., payment for diagnosis and management of back pain in a population of patients). This would be a per-patient payment for a population of patients (e.g., as part of an Accountable Care Organization's assigned or attributed patients) to manage the costs of diagnosis and treatment of certain types of symptoms, risk factors, and/or diagnosed conditions for all of those patients.
- **Specialty medical homes** (e.g., payment to support provision and coordination of both primary and specialty care for patients with inflammatory bowel disease). This

would be a single payment to a physician practice to manage all of the primary care and specialty care needs for patients with a significant chronic or acute condition.

Although these payment models may appear different on the surface, most of the structural elements of the models are similar, so that the kinds of rules, codes, claims processing systems, etc. that would need to be implemented for the procedural episodes and complex chronic disease management episodes you are considering could be relatively easily adapted for implementation of the other models, thereby giving you a much higher return on your own investment in new payment systems. These key structural elements are:

- Defining the health condition or service that will trigger the payment
- Defining the provider(s) who will be accountable for the services delivered and for the outcomes achieved using the payment
- Defining the types of patients and health conditions/diagnoses that will be included or excluded from the payment
- Defining the healthcare services to be included/excluded in the payment
- Defining which complications will be treated using the payment
- Defining how the amount of the payment will vary based on the characteristics of the patient or the treatments that are used
- Defining how quality of care will be measured

By pursuing a broad range of different payment models, the Innovation Center can help to ensure that these definitions are developed in a consistent manner across multiple payment structures. This will facilitate the ability of other payers to implement them and will avoid gaps in care across patient conditions and services.

Create an Ongoing, Collaborative Process for Defining and Implementing Payment Models Rather Than a One-Time Competitive Solicitation

In addition to the *kinds* of payment models for which you solicit applications, the *way* in which you solicit those applications and the *process* you use for reviewing, approving, and implementing them will be critical to gaining broad participation from physicians, getting proposals for truly innovative payment and delivery models, and for achieving successful implementation. I would strongly recommend that you create a process with the following characteristics:

- **Do not narrowly specify the types of applications that can be submitted.** Allow physicians the flexibility to propose payment models that can work effectively in the unique circumstances of their own communities and practice environments.
- **Allow adequate time to prepare and submit applications.** Announce any solicitation for applications well in advance of the deadline for submitting applications. Applicants need more than a few months to prepare applications, particularly if they do not even know when to expect the solicitation to be issued or what it will focus on.
- **Provide multiple opportunities to submit applications rather than a single deadline.** If a payment model application does not request grant funds, but instead proposes a change in

payment that would reduce Medicare spending, there is no need for the Innovation Center to create a competitive process, but rather it can review applications on a rolling basis. This would reduce administrative costs for CMMI and would enable applicants to submit good applications when they are ready.

- **Ask for applications in two stages.** First, ask for short applications that describe the basic concept of the payment and delivery change and present preliminary analyses showing the potential for savings to Medicare. Then, if the basic concept and analysis have merit, request a more detailed application.
- **Provide rapid feedback on the initial short applications**. Give applicants feedback and an opportunity to resubmit their application, either in the current round or in a subsequent round of applications. If applicants are not requesting grant funds but proposing to save money for Medicare, the Innovation Center should help them submit a better proposal.
- **Do not reject applications for non-substantive reasons.** Applicants who take the time to prepare applications should not see their work wasted because they fail to meet arbitrary requirements for length or formatting of the application.
- **Provide prospective applicants with data to use in preparing their applications.** It is very difficult for applicants to develop or present a strong business case to support their proposal without access to Medicare data on current utilization and spending patterns.
- **Assure applicants that if a project is approved, they will be able to continue being paid under the proposed payment model indefinitely as long as the model is not increasing Medicare spending or reducing quality.** It is unlikely that physicians will propose or implement significant changes in care or payment if they believe the new payment model will only be used temporarily and they will have to dismantle the changes they have made when the demonstration project ends.
- **Allow modifications to payment models during the course of testing, and define the purpose of "testing" differently.** The payment model is not an intervention that can be "tested." It is a mechanism for supporting a change in care. It is the change in care that will improve quality and/or reduce costs, not the payment change itself. Consequently, the Innovation Center should not attempt to "test" narrowly defined payment models, but rather it should test whether providing *more payment flexibility to physicians* and *appropriately targeted accountability* will support higher-value care delivery. If problems are identified with a particular payment model's ability to provide the appropriate flexibility and accountability, then the Innovation Center should allow modifications to the payment model to solve those problems, otherwise it will end up wasting effort evaluating a model that is already known to have failed to address the barriers it was intended to solve.

The Innovation Center has used elements of these approaches in both the Bundled Payments for Care Improvement Initiative and the Health Care Innovation Awards. The best of these techniques should be used as the basis for the process you use to solicit, review, and implement specialty payment reforms.

Answers to Specific Questions on Procedural Episode-Based Payment Opportunities

For which outpatient procedures or medical conditions should CMS consider testing a procedural episode-based payment model?

The Innovation Center should not restrict itself to any specific procedures or conditions; it should invite applications for any procedure or medical condition for which a physician practice believes it can deliver better care at lower cost with a better payment model.

What are the opportunities to improve the quality of care and reduce expenditures associated with such a model?

In general, there are two major categories of opportunities to improve quality and reduce costs that a better payment model can support:

- Enabling physicians to deliver a different mix of services to patients that will achieve better outcomes, reduce costs, or both;
- Enabling physicians to reduce avoidable complications, such as infections, that would require additional services and spending to treat.

However, the specific opportunities to improve quality and reduce spending vary from condition to condition and from community to community. The Innovation Center should not attempt to pre-define what the opportunities are, but should encourage physicians to identify specific ways they believe care could be redesigned for higher value, provide them with the data needed to analyze those opportunities, and then approve and implement payment models to support the changes.

What are important considerations in defining the episode?

For purposes of a payment model, the "episode" should be defined to include those services and avoidable events that the physician(s) who will be managing the payment can reasonably expect to control, and it should exclude services and avoidable events that the physicians *cannot* reasonably expect to control. This definition of the episode will likely be narrower than the broader definitions of episodes that currently exist and that CMS is developing for purposes of cost measurement. Although those broader definitions of episodes may make sense in looking at all costs from a patient's perspective, they will likely include services and providers that are not involved in the payment model and therefore cannot be controlled by the providers who are managing the payment. Multiple *episode payments* may be needed within a single overall *episode of care* for a patient when there is a sequence of different providers managing different phases of the episode of care.

How could accountability for drugs prescribed be factored into the payment model?

Many physicians would be willing to take accountability for how many drugs they prescribe for their patients and which drugs are chosen from those available to the patients under the patients' pharmacy benefit plan, if they have one. However, many physicians will be

unwilling to be accountable for the actual prices of the drugs or increases in the prices of the drugs since they cannot control those prices, and they will not be willing to be accountable for decisions made by a health plan or other entity about what drugs are on a formulary that may make it difficult for their patients to obtain the most cost-effective medications.

Could such a model be developed for a single medical condition where several alternative approaches exist as treatment possibilities?

Yes, a condition-based payment model can be developed for all of the care associated with a medical condition, instead of a procedure-based payment that only involves the care associated with that particular procedure. Indeed, in cases where there is a choice of treatments, a condition-based model will be preferable to a procedure-based model because it will avoid creating any perverse incentive to do more of the procedures that are covered under the narrower model. Moreover, condition-based payment models and procedure-based models can be complementary, particularly where one set of physicians chooses the procedure and another performs the procedure, by providing the appropriate division of flexibility and accountability for the two stages of decision-making about which treatment to order and then how effectively and efficiently the treatment is delivered.

However, a condition-based payment model must be appropriately risk-adjusted, particularly where different levels of severity of the condition or comorbidities are typically associated with a different mix of treatments. Risk adjustment alone will not be sufficient to deal with unique patient cases, so outlier payments will also be important.

Moreover, in order for a condition-based model to work, the physician has to be able to determine which treatment will be used. If the patient has the freedom to make that choice and chooses to ignore what the physician recommends and obtain more or different treatment on their own, then the physician should not be held responsible for the costs or quality of care for that patient.

Finally, the payment level for a condition-based model needs to be adjusted over time to accommodate the availability of new types of treatment, new evidence about the effectiveness of different treatments, and changes in the costs of individual treatments.

What quality measures should be assessed for this type of episode to ensure safe and effective care?

The quality measures used should be focused on the intended outcomes of a procedure or management of a condition; the measures selected should be designed to (a) assure patients they are not being undertreated in a payment model designed in part to control costs and (b) allow patients to choose physicians based on the best combination of cost and quality for the patient. In general, "process" and "structural" measures should not be used, because they can inappropriately restrict the physician's flexibility to redesign care for lower cost. Moreover, measures of utilization should not be included as "quality measures" if the utilization is already part of the payment model. The quality measures used should relate directly to outcomes achievable through the type of care the physicians actually provide, not to broader aspects of quality that are desirable to promote but outside the control of the providers involved with the

payment model. Whenever possible, the data for the measures should be drawn from a clinical registry, not from claims data.

In addition to choosing appropriate quality measures, appropriate benchmarks of performance on the measures need to be established. These benchmarks should not be set using absolute standards of performance unless there is clear evidence that those standards can be achieved through tools, skills, and technologies that are reasonably available to physicians. In general, benchmarks should be based on actual performance of similar physicians caring for similar patients.

How would the method for assigning responsibility for the episode to specific practitioners or practitioner groups be designed?

Payment models should be designed based on the voluntary selection by a patient of a physician to treat their condition or perform a particular procedure. Physicians cannot be expected to take accountability for patients if they only know who those patients are after the care is already delivered, which is unfortunately the way that most current "attribution" methodologies operate.

What factors would influence a practitioner's decision about whether or not to apply to participate?

The most important factors influencing whether a physician will participate in a new payment model are:

- **Sufficient Flexibility:** Whether the payment model provides the flexibility that the physician needs to redesign care in a way that will achieve the better outcomes that are sought.
- **Appropriate Accountability:** Whether the accountability required under the payment model relates directly to aspects of cost and quality that the physician can reasonably expect to control and whether the standards of performance are reasonable and achievable with the resources and flexibility available under the payment model.
- **Adequate Payment:** Whether the payment under the model is adequate to cover reasonably achievable costs and whether the payment will be sustained for a sufficiently long time to successfully implement the necessary care changes, achieve the desired results, and recover the costs of upfront investments made.
- **Protection from Insurance Risk:** Whether the payment model provides appropriate protections from insurance risk for the physician, such as risk adjustment, risk corridors, risk limits, and outlier payments.
- **Collaboration for Mutual Success:** Whether there will be a fair and collaborative process by which (a) timely, accurate, detailed information on progress is regularly shared between CMS and the physician practice, and (b) unexpected problems can be resolved between CMS and the physician practice so that implementation can continue in a way which enables CMS, the physician practice, and beneficiaries to all benefit.

How could CMS encourage the adoption of such a model among other payers?

One of the biggest barriers that both providers and other payers face in implementing new payment models is that comparable payment structures are not available from CMS, so merely offering a new Medicare payment model will encourage other payers to do the same. However, CMS can deter participation of other payers and also providers if it attempts to define a payment structure in a way that makes it difficult for other payers to use. Consequently, CMS should not attempt to define payment models in too much detail in advance, and it should allow different payment models and variations on payment models in different communities if that will enable more local payers to participate.

CMS should work with multi-stakeholder Regional Health Improvement Collaboratives in individual communities to work with other payers, employers, providers, and patients to develop payment models that can be successfully implemented by all payers.

What challenges might be encountered in implementing such a model?

There will be many challenges in implementing any new payment reform; while some can be anticipated, others cannot be. Consequently, CMS should regularly share timely, accurate, detailed information on progress with the physician practices participating in a payment model, and then work collaboratively with them to make revisions in the payment model to address any problems in a "win-win-win" way, i.e., so that Medicare, the physician practice, and beneficiaries all benefit.

What other factors should CMS consider in the development of a procedural episode-based payment model?

CMS should develop multiple models in collaboration with physicians from a wide range of specialties. CMS should not attempt to narrowly specify a particular payment model in order to "test" whether that specific approach "works;" rather, it should implement multiple models that are designed to match the specific needs of different types of patients whose care is being managed by different specialties. The "test" should be whether physicians can improve quality and lower cost for specific types of patients when the *specific* barriers *those* physicians face under the current payment system are *removed*.

Answers to Specific Questions on Complex and Chronic Disease Episode-Based Payment Models

How should CMS define a complex medical management model, both in terms of the applicable medical conditions or diseases, the services furnished, and the payment mechanism?

CMS should not limit payment reforms to "complex" medical management. Any effort to define which patients are "complex" and which are not will only create a new and inappropriate silo of payment that will inevitably result in more administrative costs and disparities in care. Some patients with a single health condition can be very complex to manage, whereas some patients with multiple health problems can be relatively easy to manage. Payment

reforms should be designed to provide flexibility to physicians to deliver the right services to patients based on both the types of health problems they have and other challenges they face in order to achieve the best outcomes at the lowest possible cost.

What specific health conditions and/or specific specialties should the model target?

The Innovation Center should not restrict payment models to any specific conditions or specialties; it should invite applications for any condition, combination of conditions, or population of patients for which a physician practice believes it can deliver better care at lower cost with a better payment model.

Would new services be required under this model in order to improve beneficiary care? If so, what are these new services and how should they be paid for under this model?

In order for a new payment model to be truly effective in transforming care, it must provide physicians with the flexibility to adjust the types, intensity, and mix of services for patients in ways that will achieve the best outcomes at the lowest cost and to target additional services to the patients who most need them. In many cases, this will require delivering services that are not currently reimbursed by Medicare (e.g., telephone calls and nursing education services to help a patient avoid an exacerbation and emergency room visit); indeed, the failure to pay for many high-value services is one of the major reasons payment reform is desperately needed in Medicare. The goal of a new payment model from Medicare should not be to identify specific "new" services to pay for, but rather to provide a more flexible payment that allows physicians to make the decision as to whether "new" or "old" services would be better for a particular patient.

How could accountability for drugs prescribed be factored into the payment model?

Many physicians would be willing to take accountability for how many drugs they prescribe for their patients and which drugs are chosen from those available to the patients under the patients' pharmacy benefit plan, if they have one. However, many physicians will be unwilling to be accountable for the actual prices of the drugs or increases in the prices of the drugs since they cannot control those prices, and they will not be willing to be accountable for decisions made by a health plan or other entity about what drugs are on a formulary that may make it difficult for their patients to obtain the most cost-effective medications.

What are the important considerations in assigning the responsibility for care (to either the comanaging specialist practitioner or the primary care practitioner) in such a model?

Payment models should be designed based on the voluntary selection by a patient of a physician or group of physicians to treat their condition or perform a particular procedure. Physicians cannot be expected to take accountability for patients if they only know who those patients are after the care is already delivered, i.e., the way most current "attribution" methodologies operate.

What quality measures should be assessed for this type of episode to ensure safe and effective care?

The quality measures used should be focused on the intended outcomes of management of the patients' health conditions; the measures selected should be designed to (a) assure patients they are not being undertreated in a payment model designed in part to control costs and (b) allow patients to choose physicians based on the best combination of cost and quality for the patient. In general, "process" and "structural" measures should not be used, because they can inappropriately restrict the physician's flexibility to redesign care for lower cost. Moreover, measures of utilization should not be included as "quality measures" if the utilization is already part of the payment model. The quality measures used should relate directly to outcomes achievable through the type of care the physicians actually provide, not to broader aspects of quality that are desirable to promote but outside the control of the providers involved with the payment model. Whenever possible, the data for the measures should be drawn from a clinical registry, not from claims data.

In addition to choosing appropriate quality measures, appropriate benchmarks of performance on the measures need to be established. These benchmarks should not be set using absolute standards of performance unless there is clear evidence that those standards can be achieved through tools, skills, and technologies that are reasonably available to physicians. In general, benchmarks should be based on actual average performance of similar physicians caring for similar patients.

What opportunities and challenges would exist in defining an episode of care?

For purposes of a payment model, the "episode" should be defined to include those services and avoidable events that the physician(s) who will be managing the payment can reasonably expect to control, and it should exclude services and avoidable events that the physicians cannot reasonably expect to control. This definition of the episode will likely be narrower than the broader definitions of episodes that currently exist and that CMS is developing. Although those broader definitions of episodes may make sense in looking at all costs from a patient's perspective, they will likely include services and providers that are not involved in the payment model and therefore cannot be controlled by the providers who are managing the payment.

What would be the distinctive characteristics between this complex medical management model and the chronic care management model discussed in the 2014 PFS final rule or other primary care initiatives currently operated by CMS?

The chronic care management fees defined in the 2014 PFS final rule are desirable additions to the current physician fee schedule, but they do not provide the kind of flexibility that physicians need to significantly redesign care for Medicare beneficiaries in order to deliver better outcomes for patients at lower cost to the Medicare program. New payment models supported by the Innovation Center should not simply create new payment codes for narrowly-defined services, but should provide physicians with more flexible, bundled payments that enable them to deliver the kinds of services supported by the chronic care management fees as well as additional or different services for patients who need them.

What factors would influence a practitioner's decision about whether or not to apply to participate?

The most important factors influencing whether a physician will participate in a new payment model are:

- **Sufficient Flexibility:** Whether the payment model provides the flexibility that the physician needs to redesign care in a way that will achieve the better outcomes that are sought.
- **Appropriate Accountability:** Whether the accountability required under the payment model relates directly to aspects of cost and quality that the physician can reasonably expect to control and whether the standards of performance are reasonable and achievable with the resources and flexibility available under the payment model.
- **Adequate Payment:** Whether the payment under the model is adequate to cover reasonably achievable costs and whether the payment will be sustained for a sufficiently long time to successfully implement the necessary care changes, achieve the desired results, and recover the costs of upfront investments made.
- **Protection from Insurance Risk:** Whether the payment model provides appropriate protections from insurance risk for the physician, such as risk adjustment, risk corridors, risk limits, and outlier payments.
- **Collaboration for Mutual Success:** Whether there will be a fair and collaborative process by which (a) timely, accurate, detailed information on progress is regularly shared between CMS and the physician practice, and (b) unexpected problems can be resolved between CMS and the physician practice so that implementation can continue in a way which enables CMS, the physician practice, and beneficiaries to all benefit.

How can CMS encourage the adoption of such a model among other payers?

One of the biggest barriers that both providers and other payers face in implementing new payment models is that comparable payment structures are not available from CMS, so merely offering a new Medicare payment model will encourage other payers to do the same. However, CMS can deter participation of other payers and also providers if it attempts to define a payment structure in a way that makes it difficult for other payers to use. Consequently, CMS should not attempt to define payment models in too much detail in advance, and it should allow different payment models and variations on payment models in different communities if that will enable more local payers to participate.

CMS should work with multi-stakeholder Regional Health Improvement Collaboratives in individual communities to work with other payers, employers, providers, and patients to develop payment models that can be successfully implemented by all payers.

What challenges might be encountered in implementing such a model?

There will be many challenges in implementing any new payment reform; while some can be anticipated, others cannot be. Consequently, CMS should regularly share timely, accurate, detailed information on progress with the physician practices participating in a payment model, and then work collaboratively with them to make revisions in the payment model to

address any problems in a "win-win-win" way, i.e., so that Medicare, the physician practice, and beneficiaries all benefit.

What other factors should CMS consider in the development of a complex medical management model?

CMS should develop multiple models in collaboration with physicians from a wide range of specialties. CMS should not attempt to narrowly specify a particular payment model in order to "test" whether that specific approach "works;" rather, it should implement multiple models that are designed to match the specific needs of different types of patients whose care is being managed by different specialties. The "test" should be whether physicians can improve quality and lower cost for specific types of patients when the specific barriers created by the current payment system are removed.

I hope the above input is helpful. I would be happy to answer any questions you may have about these recommendations or to provide any additional information you or your staff may have about them.

Sincerely,

Harold D. Miller
President and CEO