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May 25, 2018

Adam Boehler
Deputy Administrator for Quality and Innovation
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMMI Request for Information on Direct Provider Contracting Models

Dear Deputy Administrator Boehler:

It is encouraging to hear that the Center for Medicare and Medicaid Innovation is considering testing new types of alternative payment models. We commend you for seeking public input on how to best design and implement these new models.

In order to have the greatest success in "Direct Provider Contracting," we urge that you take the following four actions:

1. **Embrace a bottom-up approach to Direct Provider Contracting by implementing the physician-focused payment models that have been recommended by the Physician-Focused Payment Model Technical Advisory Committee.**

2. **Create the capacity at CMS and its MACs to implement bundled payments and other innovative approaches to Direct Provider Contracting.**

3. **Use limited-scale testing to enable the most innovative Direct Provider Contracting models to move forward quickly.**

4. **Create a faster, more efficient approach at CMMI for implementing Direct Provider Contracting models and all Alternative Payment Models.**

More detail on each of these recommendations is provided below.

1. Embrace a Bottom-Up Approach to Payment Innovation at CMS by Implementing the Payment Models Recommended by PTAC

In 2015, Congress recognized that there were too few Alternative Payment Models that were specifically designed for physicians. In the Medicare Access and CHIP Reauthorization Act (MACRA), Congress created a bottom-up approach through the Physician-Focused Payment Model Technical Advisory Committee (PTAC) that specifically welcomes payment models

designed by physicians and other practitioners and that encourages development of payment and delivery models that are feasible for small physician practices to implement.

In just 18 months, PTAC has received 25 complete proposals and an additional 14 letters of intent. It has completed reviews of 18 of the proposals, and it has recommended that a total of 10 models be tested or implemented. All of these models could be structured as Direct Provider Contracting models.

For example, the first physician-focused payment model recommended by the Physician-Focused Payment Model Technical Advisory Committee was a payment model developed by the Illinois Gastroenterology Group (IGG) in order to support better care management for patients with inflammatory bowel disease. This payment model has already been implemented as a Direct Provider Contracting model for patients insured by Blue Cross Blue Shield of Illinois, and it has resulted in better patient outcomes and significant savings for the health plan. Although the IGG proposal was focused on Crohn's Disease patients because that is one of the chronic conditions gastroenterologists treat, CMS could easily implement a similar approach with many other specialties for the chronic conditions those specialists treat, with the potential for significant total savings for Medicare and better outcomes for many beneficiaries.

CMS can make immediate progress in implementing Direct Provider Contracting models by embracing the process that Congress created and implementing the physician-focused payment models that have already been recommended by the Physician-Focused Payment Model Technical Advisory Committee.

2. Create the Capacity at CMS and its MACs to Implement Bundled Payments and Other Direct Provider Contracting Models

In most of the large Alternative Payment Models created by CMMI, physicians are expected to reduce total Medicare spending on their patients. While it is clearly easier for CMMI to pursue payment models that hold providers accountable for total Medicare spending, payment models based on total spending inappropriately place small providers and single-specialty providers at significant financial risk for things they cannot control and can discourage providers from treating patients with unusual or complex needs. Moreover, this approach can inappropriately reward a healthcare provider for failing to order or deliver a costly service that a patient needs, since the provider could receive a portion of the savings when fewer services are delivered.

A good Direct Provider Contracting model will have the following characteristics:

- **Adequate resources to support the services patients need.** Since the current fee-for-service system does not pay adequately or at all for many high-value services (e.g., communication among physicians to resolve a diagnosis or coordinate services, proactive outreach to patients to identify problems early, etc.), successful Direct Provider Contracting models need to provide additional resources to deliver these services in order for providers to reduce the use of other, more expensive services.
- **Flexibility for providers to deliver the most appropriate services.** In a successful Direct Provider Contracting model, a provider or team of providers would not be penalized financially for choosing the best combination of services for their patients.

- **Accountability for the aspects of quality and spending that the physician practice can control.** In return for adequate, flexible payments, a physician practice in a Direct Provider Contracting model will be able to accept accountability for improving quality and reducing costs, but the accountability needs to be focused on the types of outcomes and spending that the provider can control. In addition, both accountability measures and payment amounts need to be adjusted for differences in patient characteristics that affect outcomes and costs.

There is no single Direct Provider Contracting model that will work for all types of patients and all types of healthcare providers. Different medical specialties treat different kinds of health problems, and the opportunities to improve quality and reduce costs will differ for the different types of health problems addressed by physicians within each specialty and subspecialty. Moreover, the care delivery changes that are needed to address these opportunities will also differ by specialty, as will the barriers in the current payment system that need to be overcome in order for physicians, hospitals, and other healthcare providers to redesign care delivery for their patients.

However, a relatively small number of Direct Provider Contracting models will likely be able to enable most physician practices and other providers to address the vast majority of patient needs. The American Medical Association and CHQPR identified seven types of physician-focused payment models that can be used to address the most common types of opportunities and barriers that exist across all physician specialties. These are:

1. **Payment for a High-Value Service.** A physician practice would be paid for delivering one or more desirable services that are not currently billable, and in return, the practice would take accountability for controlling the use of other, avoidable services for its patients.
2. **Condition-Based Payment for Physician Services.** A physician practice would receive a bundled payment that provides the flexibility to use the diagnostic or treatment options that address a patient's condition most efficiently and effectively without concern that using lower-cost options would harm the operating margins of the practice.
3. **Multi-Physician Bundled Payment.** Two or more physicians who are providing complementary diagnostic or treatment services to a patient would have the flexibility to redesign those services in ways that would enable high-quality care to be delivered as efficiently as possible.
4. **Physician-Facility Procedure Bundle.** This model would allow a physician who delivers a procedure at a hospital or other facility to choose the most appropriate facility for the treatment and it would give the physician and facility the flexibility to deliver the procedure in the most efficient and high-quality way.
5. **Warrantied Payment for Physician Services.** This model would give a physician practice the flexibility and accountability to deliver care with as few avoidable complications as possible.
6. **Episode Payment for a Procedure.** This model would enable a physician who is delivering a particular procedure to work collaboratively with the other providers delivering services related to the procedure (e.g., the facility where the procedure is performed, other physicians who are involved in the procedure, physicians and facilities who are involved in the patient's

recovery or in treating complications of the procedure, etc.) in order to improve outcomes and control the total spending associated with the procedure.

7. **Condition-Based Payment.** A physician practice would have the flexibility to use the diagnosis or treatment options that address a particular health condition (or combination of conditions) most efficiently and effectively and to work collaboratively with other providers who deliver services for the patient's condition in order to improve outcomes and control the total spending associated with care for the condition. Condition-based payments are the most patient-centered Direct Provider Contracting models and provide the greatest opportunities to improve outcomes and control spending.

Additional details on these payment models and examples of how they are being used are available in *A Guide to Physician-Focused Alternative Payment Models*, which is available at http://www.chqpr.org/downloads/Physician-FocusedAlternativePaymentModels.pdf.

Unfortunately, CMS cannot currently implement most of these types of models as Direct Provider Contracting models because its current claims payment systems do not support them. Failing to make investments in the administrative systems needed to implement new payment models is penny-wise and pound-foolish, because the potential savings from better payment models will far exceed the costs of implementing them.

CMS and its Medicare Administrative Contractors (MACs) should quickly make any changes needed in Medicare claims payment and other administrative systems to support implementation of all seven of these payment models as Direct Provider Contracting models. This would not only ensure that CMS can quickly implement a wide range of Direct Provider Contracting models, but it would encourage physician practices, medical specialty societies, and others to design payment models in a common framework, which will reduce implementation costs for CMS.

In addition, **CMS should revise the definition of "financial risk" for Advanced APMs in the MACRA regulations to enable design of Direct Provider Contracting models that small physician practices can feasibly participate in.** In MACRA, Congress required that in order for a physician to be exempt from MIPS and to qualify for the bonus payments authorized by Congress, the alternative payment entity receiving the payment must bear "financial risk for monetary losses … that are in excess of a nominal amount." The risks incurred when a physician practice participates in an alternative payment model are a function of both the *costs that the practice incurs* to implement the model and the *revenues it receives under the model*. If the practice hires or pays for new staff to deliver services to patients under the alternative payment model, if it acquires new or different equipment to deliver services, or if it incurs increased administrative expenses to implement the alternative payment model, and if those expenses are not automatically or directly reimbursed by Medicare, then the practice is accepting financial risk for monetary losses. Therefore, to encourage participation in Direct Provider Contracting models, CMS regulations defining risk should be revised to include consideration of the increased costs a practice incurs, not just increases in Medicare spending. CMS should also lower the requirement that a practice pay CMS as much as 8% of its revenue when spending increases, since that represents *substantial* financial risk, not just "more than nominal risk."

3. Use Limited Scale Testing to Accelerate Innovation

Although most good Direct Provider Contracting models will likely look like one of the models in the seven categories above, the parameters of the model – the payment amounts, the specific services included and excluded, and the accountability measures – will differ depending on the specific patients, conditions, services, and communities where the model will be used. For example, although oncologists and cardiologists could each use a form of condition-based Direct Provider Contracting to improve care for their patients and reduce spending for Medicare, the types of treatments that will be paid for and the outcomes to be achieved will differ significantly between patients with cancer and patients with heart failure, and so the payment amounts and performance measures in the models will also need to be different.

In most cases, however, physician practices face a "chicken and egg" conundrum in defining a Direct Provider Contracting model for specific types of conditions, procedures, and patients. Fully specifying the parameters of the model requires information that can only be obtained from practices that are delivering services in a different way, but the practices cannot deliver services in that way without having an alternative payment model to support them. For example:

- **Determining appropriate payment amounts for new or different services.** If a Direct Provider Contracting model is going to support the delivery of a service that is not currently eligible for payment under current Medicare payment systems, the model will need to specify how much will be paid for that service. However, it is difficult to estimate the cost of such a service if there is little or no experience in delivering the service due to lack of payment. For example, a payment model might be designed to pay a non-clinician educator to educate a chronic disease patient about how to avoid exacerbations, but it will not be clear how many patients can be adequately educated by a single individual, how much will need to be paid for an educator with the skills necessary to be effective, etc. until the model is actually implemented.
- **Setting payment amounts for bundled services.** If a Direct Provider Contracting model provides a bundled payment that replaces one or more current Medicare payments and also provides flexibility to deliver services that are not currently eligible for payment, the model needs to specify how much will be paid for the bundle. However, it is difficult to estimate the appropriate payment amount without an understanding of how often current services would be replaced by new services, the extent to which fixed costs supporting existing services can be eliminated, etc. For example, many physicians would prefer a Direct Provider Contracting model that replaces current Evaluation & Management payments (which are limited to face-to-face visits with a physician) with a monthly payment that would provide the flexibility to schedule patient phone calls with the physician instead of just office visits, to make contacts with patients using nurses instead of physicians, etc. However, it will not be clear how large these monthly payments should be until it is determined what proportion of office visits can be eliminated, what types of additional staff of the practice, etc., and those changes cannot be made until the model is actually implemented.
- **Defining methodologies for risk-adjusting/stratifying payments.** A Direct Provider Contracting model that creates a bundled payment in place of fees for individual services will likely need to stratify or adjust the bundled payment amount to reflect differences in patient needs. However, the patient characteristics that affect the level of services may not be adequately captured by ICD-10 diagnosis codes. The model would need to specify what

combination of patient characteristics would be associated with each payment stratum and how much the payment amount would be, but it is difficult to do either of these things without data on how many patients have particular combinations of characteristics and how the appropriate services will differ for different characteristics. For example, a Direct Provider Contracting model might create a monthly payment to support home-based palliative care services to patients, but the payment amounts would need to be higher for patients with lower functional status, less caregiver support, etc., and it will not be clear how many patients have those characteristics and how many patients in each category could be managed by a palliative care team until the model is actually implemented.

- **Setting standards for performance on outcomes.** There is broad agreement that it would be desirable to have payment models that are designed to improve patient outcomes. However, there is little outcome data available that can be used for establishing baseline levels of outcomes and performance standards because of the significant costs involved in collecting outcome data and the lack of a business case for providers to incur those costs under current payment systems. For example, a Direct Provider Contracting model might provide a flexible payment for managing knee or hip osteoarthritis that encourages use of alternatives to surgery; the payment model would need to hold providers accountable for addressing pain and mobility problems in order to ensure they were not stinting on services, but data on expected levels of pain and mobility would not be available until they were collected through implementation of the model.

Currently, CMMI will only test a payment model if it projects that the model will reduce Medicare spending. However, since it is impossible to confidently make such a projection without specifying the parameters of the model, CMMI's current approach means that most innovative models will never be tested.

To address this problem, **CMMI should create a process for "limited scale testing" of innovative Direct Provider Contracting models**. The following five-step process should be used:

1. **Selection of Pilot Sites for Limited-Scale Testing.** When CMMI is presented with a proposal for a promising Direct Provider Contracting model (e.g., a proposal that has been recommended by the Physician-Focused Payment Model Technical Advisory Committee) where the information needed to fully specify the parameters or to estimate impacts cannot be obtained without implementing the model on a limited scale, CMMI should issue a public call for physician practices or other provider organizations to volunteer to serve as pilot test sites. It should then select a small group of the volunteers who: (1) collectively serve a sufficiently large number of eligible Medicare beneficiaries to provide reasonably reliable data for setting the model parameters; (2) are reasonably representative of the diversity of practice structures that would be eligible to participate in the model if it were made widely available, (3) are located in different parts of the country that differ in terms of market structure, practice patterns, etc., and (4) are willing to collect the data necessary to set the model parameters and to participate in a formative evaluation process.
2. **Implementation of Direct Provider Contracting Models at the Pilot Sites.** CMMI and the pilot sites should agree on a set of initial "best guesses" for the parameters of the Direct Provider Contracting models. The pilot sites would start delivering care as the model intends, they would assess patients and assign them to payment categories using the initial

definitions of those categories, and they would bill CMS for payments under the model using the initial amounts. There would be an explicit understanding that the payment amounts would probably not be "right" initially, and so there would be a collaborative effort between CMMI and the pilot sites to assess the payment parameters frequently during the limited-scale testing process and to adjust the parameters as necessary in order to ensure that patients are receiving high-quality care and that the pilot sites are neither being financially harmed nor receiving financial windfalls at Medicare's expense. This would be consistent with CMMI's commitment to rapid cycle evaluation of payment models.

3. **Collection of Data for Refining Parameters.** The pilot sites should collect data on the time and resources involved in providing services to the patients, information on patient outcomes, etc. in order to refine the model parameters. Ideally, all or part of the cost of the data collection activities would be covered using funds or other assistance provided by CMMI.

4. **Decision About Broader-Scale Testing or Implementation of a Refined Model.** Following a period of limited scale testing, a decision would be made by CMS as to whether to pursue testing of a revised version of the Direct Provider Contracting model with sufficiently broad participation to enable a summative evaluation of its impact on spending and quality. This decision would be based on the results of the formative evaluation as to the desirability of the model for patients, for physician practices, and for CMS. In some cases, the benefits of the Direct Provider Contracting model in terms of savings and quality improvement will be sufficiently large that it will be appropriate to immediately make the model available to all interested providers and then monitor and refine it over time.

5. **Transition of Pilot Sites.** In order to encourage providers to serve as pilot sites, CMS should make a commitment to them that if a decision is made to terminate continued development and testing of the Direct Provider Contracting model, a plan will be developed that would enable the pilot sites to transition out of the limited-scale testing process and return to standard payment systems without incurring any financial losses.

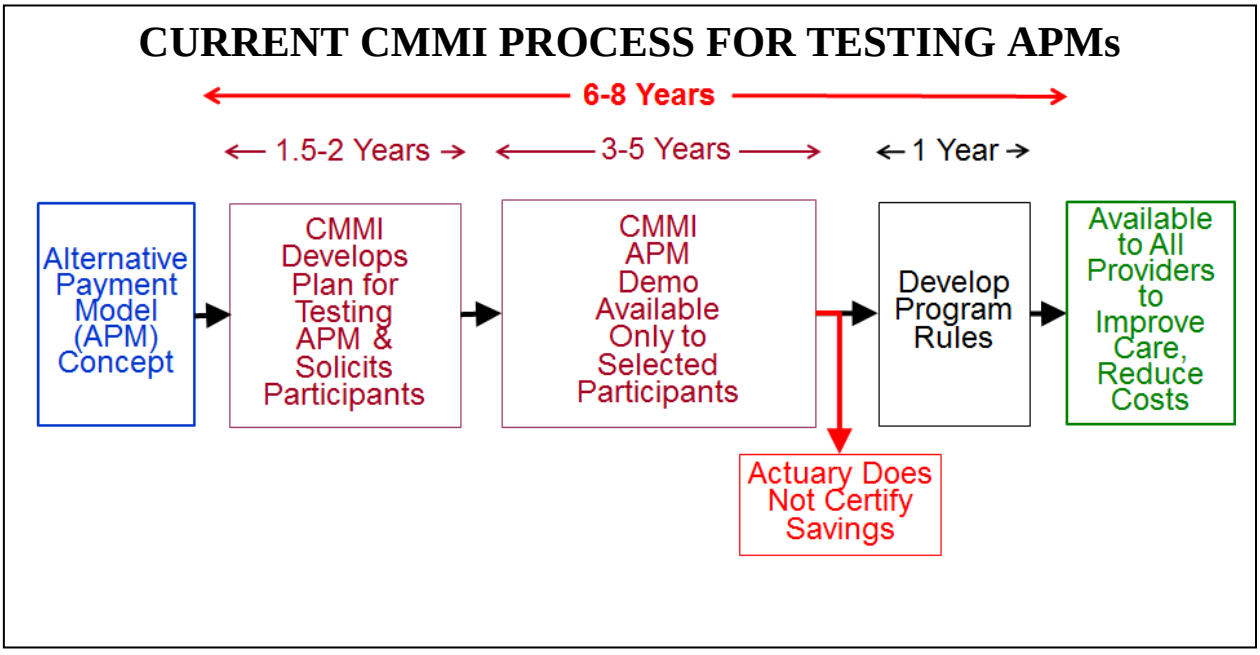
CMMI's authorizing statute clearly permits this type of limited-scale testing. There are no limits in the law as to (1) how many providers can participate in testing, (2) how the evaluation should be conducted, (3) how quickly a determination must be made as to whether the model improves quality or reduces spending, or (4) how often the design of a model can be modified before it is terminated or expanded. In fact, CMMI is prohibited from requiring that a model be designed to be budget neutral initially, and the law authorizes CMMI to modify the design and implementation of a model after testing has begun if the model is not expected to either improve quality without increasing spending or reduce spending without reducing quality.

Moreover, CMMI has already demonstrated the ability to simultaneously implement limited-scale testing for large numbers of care delivery improvement projects. Through two rounds of Health Care Innovation Awards (HCIA) in 2012 and 2014, the Innovation Center provided grant funds to support the implementation of 146 pilot projects testing innovative approaches to care delivery across a wide range of medical conditions. Many of the HCIA awards demonstrated that significant improvements in quality and reductions in spending were possible if healthcare providers could receive the resources they needed to deliver care differently. However, none of the HCIA awards implemented a payment model that would enable continuation of the approach developed in the project beyond the award period and the expansion of the same approach to other sites. Moreover, while the HCIA grant funds could enable providers to pay for services

that are not reimbursable under the fee-for-service system, the grants did not eliminate the financial penalties providers would face if they reduced reimbursable services. Therefore, it is essential for CMMI to expand the use of limited-scale testing to Direct Provider Contracting models.

4. Create a Faster, More Efficient Approach for Implementing Direct Provider Contracting Models

To date, when CMMI has decided to pursue development and testing of a new payment model, the process it uses is extremely long, complex, and resource-intensive. This not only slows down the process of testing and implementation but it reduces the number of models that CMMI can or will test. Although many proposals for innovative alternative payment models have been submitted to CMMI, most have not been implemented even after many months of discussion with CMMI staff and despite efforts to modify proposals to address concerns raised by CMMI. Once CMMI decides to pursue a payment demonstration, it typically takes 18-24 months or more from the time an initiative is first announced to the time when providers actually begin to receive different payments. Even if a payment model is succeeding and other providers would like to participate, the evaluation process will take 3-5 years to complete before a decision is made as to whether a payment model should be continued or expanded. As a result, under the current process for implementing new payment models, it could take 6-8 years to make a desirable Direct Provider Contracting model broadly available.



In addition, healthcare providers report that the process of applying to participate in CMMI payment models is very burdensome. Providers are expected to complete lengthy application forms requiring submission of data and other information that is expensive and time-consuming to assemble, and applications may be rejected for failure to meet non-substantive requirements such as maximum page limits. Applicants may be required to respond within a few days to CMMI's requests for more information, but the applicants receive no commitment from CMMI

as to when it will make a decision regarding their application. This uncertainty makes it difficult for a provider organization to know whether and when to start preparing for participation; starting preparation too soon could mean significant financial losses if the applicant is not accepted, whereas waiting until an application is approved to begin implementation planning could make it difficult for the provider organization to generate savings and quality improvements in the timeframes required in the demonstration.

Once accepted into a CMMI payment model, providers have been required to assemble and submit large amounts of data and to participate in a variety of meetings; these administrative activities can involve significant costs for providers and/or take significant amounts of their time away from patient care. There is generally little or no compensation provided to practices to offset these costs, even though CMMI spends tens of millions of dollars to pay the consultants who review the information the providers submit and organize the meetings they attend. Many providers, particularly small providers, have decided not to even apply to participate in otherwise desirable CMMI programs and others have dropped out of the programs in the early phases solely or partly because of the cost and time burden of participating.

Providers who do participate in CMMI payment models are told they can only count on the new payments lasting for a few years; the payments will only be continued beyond that if an evaluation proves that the program has saved money for the Medicare program. While this might sound like a very prudent approach, it can have the perverse effect of reducing the chances of significant success. Physicians, hospitals, and other healthcare providers are unlikely to fundamentally change the way they deliver care in response to a payment change that may only last a few years, and it is impossible to measure longer-term impacts on outcomes during an evaluation period that lasts only a few years.

CMMI has only been able to initiate testing of a few payment models each year because of the elaborate and expensive structure of monitoring and evaluation contractors and learning networks for providers that it creates for each model. More than half of the funds spent from CMMI's appropriation have been used to pay for planning, research, evaluation, and technical assistance activities, rather than for payments to providers to improve the delivery of care.

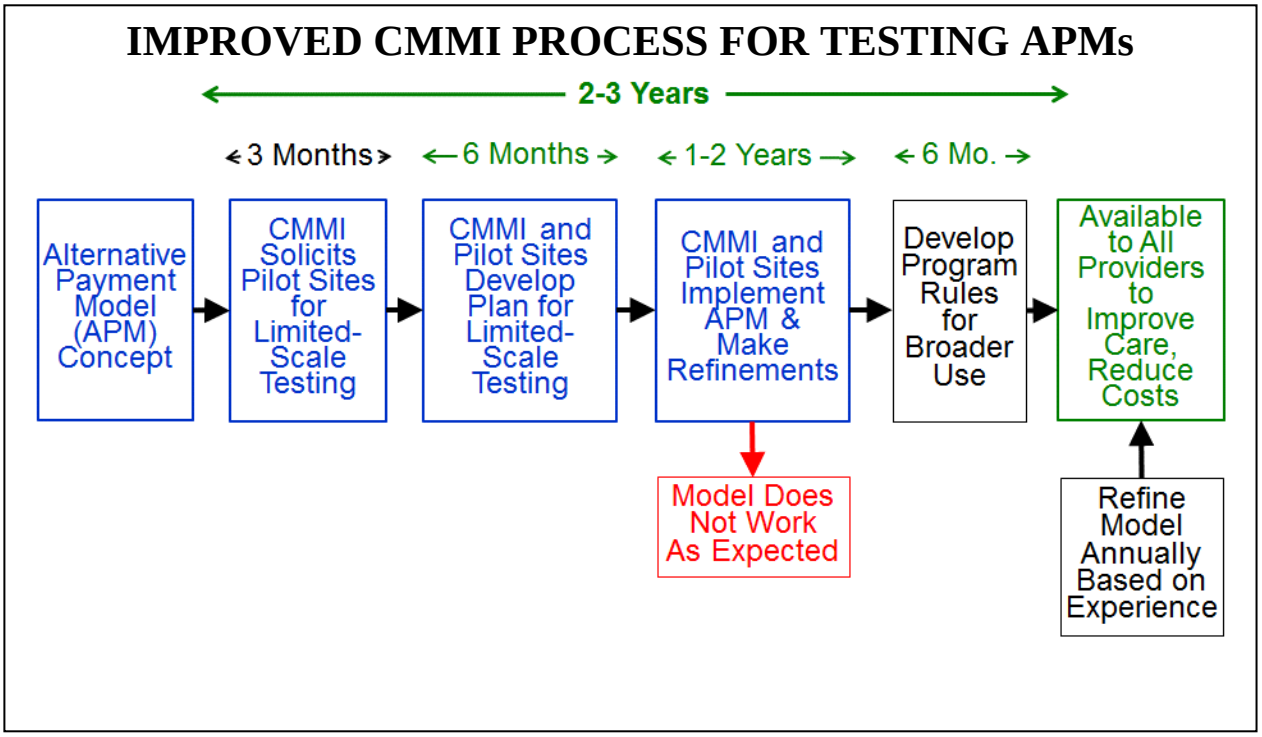
If CMMI continues to use this same process for testing and implementing alternative payment models in the future, it would take a decade before the majority of physicians in the country would have the ability to participate in a Direct Provider Contracting model designed for the types of patients they care for. This would also mean that relatively few Medicare beneficiaries could benefit from the higher quality care that would be possible under good Direct Provider Contracting models and that the Medicare program would not achieve the significant savings that wider use of such a model could generate.

CMMI should completely redesign the processes it uses to test and implement alternative payment models in order to achieve the goals that are implicit in MACRA – every physician should have the opportunity to receive at least 25% of their revenues from well-designed alternative payment models in 2019, at least 50% of their revenues from APMs in 2021, and at least 75% of their revenues from APMs in 2023.

Just as many physicians, hospitals, and other healthcare providers are now re-engineering their care delivery processes to eliminate steps that do not add significant value, CMMI should use

Lean design techniques and other approaches to identify and eliminate all steps and requirements in its implementation processes that do not add value or that impede achieving the goals that Congress has set. Moreover, reducing the number of consulting contracts on projects will free up CMMI staff time and funds so that more Direct Provider Contracting models and other APMs can be implemented simultaneously.

As part of the redesign process, CMMI should also look for ways to reduce the administrative requirements it imposes on providers participating in Direct Provider Contracting models. As noted earlier, the administrative burdens in many existing models discourages participation, particularly by small providers, and the burdens reduce the ability of providers to make the care improvements needed to achieve success under the model.



To ensure that the MACRA goals are achieved, CMS should establish specific milestones that are designed to implement as many Direct Provider Contracting models as possible and as quickly as possible. For example, the following timetable would allow such models to be made broadly available within 2-3 years after a proposed model is submitted to CMMI:

- When a desirable Direct Provider Contracting model is proposed (e.g., when a physician-focused alternative payment model is recommended by the PTAC), CMMI should recruit and select initial pilot sites within 90 days.
- CMMI should then work collaboratively with the pilot sites to develop the initial parameters for implementing the model. This process should not take more than six months.
- Over the next 12 to 24 months, the pilot sites would be paid through the Direct Provider Contracting model and use the new payments to restructure the way they deliver care. CMMI and the pilot sites would work together to continuously refine the details of the

APM to ensure it results in a "win-win-win" for the patients, the pilot sites, and the Medicare program.

- Assuming the results produced at the initial pilot sites confirm the desirability of the model, CMMI would then develop the rules and procedures needed so that a larger number of providers could apply to participate in the Direct Provider Contracting model. This would be completed within 6 months.
- Interested providers should then be permitted to apply to participate in the Direct Provider Contracting model no less frequently than twice per year. Applications to participate should be reviewed and approved or rejected by CMMI within 60 days. Applications should only be rejected if an applicant cannot demonstrate that it has the ability to implement the model, not because of arbitrary limits on the size of the program.

Once a physician practice begins to participate in a Direct Provider Contracting model, it should be permitted to continue doing so as long as it wishes to do so, unless CMS can demonstrate that Medicare spending under the payment model is higher than it would be under the standard physician fee schedule or that the quality of care for beneficiaries is being harmed. It is unlikely that physician practices will be willing to implement significant changes in care delivery if they believe the payment model will only be available for a short period of time and that they will have to dismantle the changes they have made when the demonstration project ends. Section 1115A of the Social Security Act explicitly permits the Secretary of HHS to continue a payment model as long as the model is expected to improve the quality of care without increasing spending, reduce spending without reducing the quality of care, or improve the quality of care and reduce spending. Moreover, if a payment model is not achieving these goals, the law gives the Secretary of HHS the power to modify the payment model rather than terminate it. Decisions to continue or modify a model can be made before an evaluation of the model is completed.

In many cases, there may be no need for additional "testing" of a model before it is made broadly available to providers who wish to participate. If a Direct Provider Contracting model is explicitly structured to assure CMS that Medicare spending would be lower than it would otherwise be, if sufficient data exist to set the parameters of the model, and if a large number of physicians, hospitals, and/or other providers want to participate in the model, then it would be in the interests of beneficiaries and the Medicare program to allow as many providers to participate as are willing to do so.

New Direct Provider Contracting models could be monitored and regularly adjusted to correct any unanticipated problems and to adapt them as new technologies and research results appear. If at any point, CMS identifies a situation where quality is being harmed for a particular practice's patients, or where spending is not truly being reduced, that practice's participation in the payment model could be terminated, similar to what CMS can do today in its standard payment systems.

However, similar to the way Congress established the Medicare Shared Savings Program, physicians, hospitals, and providers should have the choice of whether to participate in Direct Provider Contracting models or to continue delivering services under the standard fee-for-service payment system. Not every physician or hospital would need to participate in a Direct Provider Contracting model in order for the Medicare program to achieve significant savings, and it is

likely that better results will be achieved by willing participants than by those who are forced to participate.

Thank you for the opportunity to comment. We would be happy to provide additional information on these recommendations and any assistance that you would find helpful in implementing them.

Sincerely,

Harold D. Miller
President and CEO