June 6, 2011

THEDACARE
CENTER FOR
HEALTHCARE VALUE
Targeting Value. Spreading Change.

Donald Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1345-P: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

The ThedaCare Center for Healthcare Value (hereinafter the Center) has a mission to create a healthcare marketplace that rewards providers for delivering value to patients. The Center defines value as delivering the highest quality care at the lowest possible cost. To achieve a value-focused healthcare system, the Center is a national advocate for payment reform, delivery reform and transparency.

In combination with its policy advocacy work, the Center works with provider systems across the country to improve quality and reduce costs using the Lean process improvement system. The Center manages three networks of twelve provider systems that are focused on improvement through the Lean system. The Center teaches transformation leadership using the lessons and firsthand experience gained by the ThedaCare Health System through our and others Lean quality journey.

The ThedaCare Health System is an example of how remarkable delivery system reform can be achieved. Using the Lean system, the ThedaCare Health System helped reduce costs by over $27 million and simultaneously improved quality. A specific example is a new Collaborative Care unit that reduced the average cost per case by 21 percent. At the same time, ThedaCare Health System reached important quality improvement targets, including meeting a key Pneumonia quality measure 100% of the time (up from 38%), reducing medication reconciliation errors by 99%, improving patient satisfaction from 68% to 87%, and reducing the average length of stay from 3.71 days to 2.96 days.

Beyond ThedaCare Health System's specific successes in process redesign and improving the patient experience of care, while simultaneously lowering costs, the Partnership for Healthcare Payment Reform (PHPR) has brought together payers, providers, employers, and state officials to design specific pilots to test payment reform. Specifically, PHPR has designed two payment pilots: (1) a bundled payment methodology for total knee replacement; and (2) a shared savings payment that transitions into an episode of care payment for diabetes management in adults patients. Through the payment redesign process we have considered many of the elements of lowering cost and improving quality that CMS and the CMMI are considering for the MSSP and Pioneer ACO programs. We believe that the lessons learned from bringing these stakeholders to the table to design new payment methodologies can be instructive for CMS and the CMMI in designing the ACO programs.

We believe that a properly structured ACO can redesign the processes of care and move toward new payment models, leading to the types of results ThedaCare and others have seen in terms of improving care for Medicare beneficiaries and lowering costs. However, we caution that the design of the program must contain certain crucial elements to creating true delivery system reforms. As a guiding principle, we encourage CMS and the Center for Medicare & Medicaid Innovation (CMMI or Innovation Center) to focus on how ACOs can best serve patients. We believe the dialogue surrounding ACOs to date has focused too intensely on the ACO's organizational structure and provider-related issues rather than focusing on Medicare beneficiaries who receive care from the ACO. We cannot over-emphasize the importance of patient-centeredness and beneficiary satisfaction in building successful ACOs. Second, we hope that the agency will ultimately adopt an approach that is flexible, allowing different ACOs in different markets the freedom to adopt the innovations and reforms that are best suited to meet the needs of their patients. We are encouraged by the announcement of the Pioneer ACO model and the flexibility that program appears to provide. We hope that program will be implemented in a way that permits testing of a broad range of payment models. Finally, based on our experience, we believe that ACOs will not succeed unless patients are engaged in their care, ACOs put the customer first, and waste is eliminated from the system.

The Center remains concerned about the potential longevity of the shared savings ACO model. For example, even if ACOs are able to achieve shared savings payments in the first three-years of their contract, we question whether such savings can be achieved over multiple subsequent three-year contract periods. However, we believe that the MSSP model ACOs can successfully transition along a continuum of payment methodologies from shared savings to episode of care payments – similar to the PHPR chronic care pilot, described above. We believe that allowing ACOs to progress from shared savings to other payment models will maximize the success of the program over the long term. The Pioneer ACO program has the potential to provide valuable lessons in this regard through its transition to population-based payments in the later years of the program. However, we encourage CMS and the CMMI to be flexible in the payment methodologies tested through the Pioneer program and to consider incorporating episode of care and bundled payment methodologies.

In order for the Medicare Shared Savings Program (MSSP) proposed rule to be successful in achieving the levels of participation the agency anticipates, the proposed rule should be modified. Below, we have outlined our comments on key aspects of the proposed rule including patient assignment, quality measurement and reporting, ACO payment, and patient-centeredness criteria. We believe that by addressing these aspects of the program, CMS and the CMMI can ensure broader participation by providers, greater involvement by patients, and a greater impact on cost in the delivery system.

Recommended Modifications to the Medicare Shared Savings Program

Beneficiary Assignment (§ 425.6)

Under the proposed rule, beneficiaries are retrospectively assigned to an ACO based on their utilization of primary care services provided by a primary care physician. Primary care physicians are defined to include physicians with a primary specialty designation of internal

medicine, general practice, family practice or geriatric medicine.[1] CMS states in the MSSP proposed rule that it is adopting a "combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period."[2] CMS goes on to say that it believes that "providing data on those beneficiaries that are assigned to an ACO in the benchmark period is a good compromise that will allow ACOs to have information on the population they will likely be responsible for in order to target their care improvements to that population while still not encouraging ACOs to limit their care improvement activities to only the subset of beneficiaries they believe will be assigned to them in the performance year."[3] We have several recommendations to improve the beneficiary assignment feature of the MSSP ACO program.

First, we believe that the definition of primary care physician is too narrow to capture the broad range of physicians and ancillary providers who actually provide primary care services to patients. Specifically, the agency should include gynecology in the list of primary care physicians for assignment purposes. Furthermore, the MSSP proposed rule fails to acknowledge the ancillary providers of primary care services, such as nurse practitioners and physician assistants. In our experience, many patients receive primary care services from these ancillary providers and would in fact identify the ancillary provider as their primary care provider, if asked to do so. Therefore, we believe that these providers must be included in the assignment methodology and should be included with the same considerations as primary care physicians. We believe that expanding the assignment methodology to include these other providers of primary care will enable ACOs to serve the largest number of Medicare beneficiaries, benefitting a wider number of patients and allowing ACOs to more successfully control costs through the use of existing provider-patient relationships.

Second, we believe that retrospective assignment poses significant challenges to ACOs who seek to improve processes of care for assigned beneficiaries. Knowing which beneficiaries are assigned to the ACO in advance of the performance period enables providers to target care and to better understand patient outcomes. If the population is not defined prior to the performance period, it is difficult to measure whether the care coordination or other process changes have actually improved care. Many interventions do not work and it is critically important that ACOs understand which ones do and without prospective analysis we simply cannot know. Without an ability to prospectively measure results, it will be difficult to sustain desired results because it will be unclear what ACOs may have done to achieve those results. In the PHPR pilot designs, both programs implement prospective assignment. For example, the acute care pilot uses a set of eligibility criteria to screen patients and assign them to the program. We believe that these pilots will show that the improvements in care processes resulting from the pilot program benefit all patients, even with the use of a prospective assignment methodology. In light of these considerations, we recommend replacing the retrospective assignment feature with prospective assignment.

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[1] § 425.4 Definitions.

[2] MSSP Proposed Rule, 19,566.

[3] *Id.*

As an alternative to the various assignment methodologies described in the preamble to the rule, we recommend an assignment methodology that uses greater patient participation. Specifically, we believe that assignment should be based on the beneficiary's identification of their primary care provider or medical home. Having patients identify their primary care physician for ACO assignment purposes would streamline other aspects of the MSSP proposed rule, such as informing beneficiaries about the ACO's use of health information and implementing patient-centeredness requirements. Because nearly 80 percent of patients have a primary care physician, we believe that this assignment methodology would result in the assignment of a large number of Medicare FFS beneficiaries and permit those patients to engage with their providers in achieving their health care goals. We believe this is a favorable mechanism to the alternatives provided in the rule and will result in the greatest potential success for the program. Notably, this approach does not limit patient choice--the beneficiary can change primary doctors at any time--it simply establishes who the patient believes their primary care doctor to be.

Quality Measurement and Reporting (§ 425.10)

In order to qualify for shared savings, ACOs are required to report on 65 quality measures in five domains and achieve a certain performance score. According to the proposed rule, CMS will designate quality performance standards for each domain's contribution to an overall ACO performance score.

The Center is concerned that the proposed methodology does not make clear to the ACO up front the quality standard the ACO is required to meet in order to receive shared savings payments. We believe that without known targets, it will be incredibly difficult for providers to achieve the quality performance threshold and thus qualify for payments based on quality achievement. We believe that it is difficult for providers to decide whether or not to participate in the program without knowing the quality targets, which are determinative of shared savings payment. We also agree with the PGP demonstration organizations' concerns relating to the proposed quality standards for ACOs. In their May 12th letter the PGP sites stated their concerns with the large number of measures proposed to go into effect in the first program year. The letter states that "[a]s an example, *on average*, it costs about $30,000 just to program a single new quality metric. This NPRM has more than 60 new ones, which equates to nearly $2,000,000 for each organization. The excellent results produced by the PGP demonstration are evidence of the benefits of a careful expansion of quality measures."[4] We are similarly concerned with the number of measures proposed and the potential impact on provider organizations who seek to participate in this program.

In the PHPR pilots, providers' quality performance targets will be set in advance using data reported by the Wisconsin Collaborative for Healthcare Quality in the Fall 2011 performance period. The quality scores reported in this period will be used to set the baseline for the following performance year. In this way, providers always know the targets they are striving to meet and know where they stand in relation to the target from the beginning of the performance period. We believe that this facilitates provider participation in the program and, in

[4] Letter from Physician Group Practice Demonstration Groups to CMS Administrator Donald Berwick (May 12, 2011).

combination with the data provided to participants (described in greater detail below) gives participating providers a chance to correct care processes mid-course to better ensure that they can meet the targets.

Finally, we recommend that the agency consider providing quality points for ACO's that improve over the course of a performance year, in addition to awarding points for the ACO achieving a certain performance threshold. This concept of applying both an achievement and an improvement score is used in the hospital value-based purchasing program and should similarly be used in the MSSP for quality scoring.

Payment specifics

Establishing a Benchmark - Risk Adjustment Methodology

In the MSSP proposed rule, CMS would use a single benchmark risk score for all three years of the ACO's agreement. CMS plans to calculate the risk score by applying the CMS-HCC model to the historically assigned beneficiary population. However, this risk score would not be annually updated. CMS states that this approach is intended to mitigate incentives to code more fully, thereby optimizing risk scores to increase shared savings. CMS also indicates its belief that this approach is reasonable because risk is relatively stable over time.

We believe that this proposed risk adjustment methodology poses significant difficulties for the successful operation of the program. If there is no risk adjustment in the performance years, ACOs that treat sicker patients will be penalized, therefore resulting in an incentive to avoid treatment of these sicker patients, or face a financial loss for doing so. The Center strongly urges CMS to reconsider this policy and to instead incorporate changes to the risk score during each of the performance years.

Payment Track 1 and Payment Track 2 (§ 425.7)

In the MSSP proposed rule, CMS establishes two separate payment tracks for Shared Savings ACOs. In Track One, ACOs are eligible for shared savings only in performance years one and two and are eligible for shared savings and at risk for shared losses in performance year three. In Track Two, ACOs are eligible for shared savings and at risk for shared losses in all three performance years.

We believe that the MSSP has the potential to reform the way many entities are delivering care and offers a new opportunity for providers to build, test and improve aspects of the care delivery process. For many potential ACOs, these processes will be new, untested and unfamiliar. Furthermore, many of these organizations will have little to no experience with assuming risk. The MSSP provides an entry point for many in the health care industry to coordinate care, manage disease, and implement infrastructure that they have not used before. Therefore, we believe that it is premature to require that these organizations take on financial risk at the beginning of the program. The Center recommends substantially reworking the two payment tracks.

Instead, Track One should consist of a pure shared savings model. Rather than requiring these ACOs to accept risk in year three, CMS should provide data to these ACOs as to what their

shared losses would have been, but should not require that these Track One ACOs share in losses. In Track Two, we recommend that ACO's be eligible to share in savings in performance years one and two and similarly receive data regarding what their share of losses would have been had they been exposed to downside risk. In performance year three, Track Two ACOs would be eligible to share in savings and at risk for a share of losses.

Net Savings Threshold (§ 425.7(c)(2))

CMS proposes requiring ACOs to exceed a minimum savings rate that would range from 2 percent to 3.9 percent in the one-sided model depending upon the number of patients assigned to the ACO. Once the ACO crosses the MSR threshold, ACOs in the one-sided model would be eligible to share in savings in excess of a two percent threshold, unless the ACO meets certain exceptions. In the two-sided model, ACOs are eligible for first dollar savings. The Center recommends eliminating the net savings threshold and instead making all ACOs eligible for first dollar savings.

Quality Performance Sharing Rate (§425.7(c)(6); (d)(5))

The MSSP proposed rule would permit an ACO that meets all requirements to share in savings of up to 50 percent in the one-sided model and up to 60 percent in the two-sided model. We believe that this percentage is too low to incentivize provider participation in the program. The Center believes that the sharing rate in Track one should be 70 percent. We believe that to provide an additional incentive for accepting risk in Track Two, the sharing rate should be 90 percent.

The PHPR chronic care pilot makes providers eligible for up to 75 percent of the shared savings amount depending upon their performance on quality measures. We believe that this amount provides an appropriate incentive for participation and improvement among participating providers. Our recommendations for increasing the sharing rate are based upon the PHPR's development of the chronic care pilot and the additional incentives necessary to encourage providers to accept risk.

Performance payment limits (§ 425.7(c)(8);(d)(7)

The MSSP proposed rule establishes a performance payment limit on the amount of shared savings an eligible ACO may receive under the one-sided and two-sided models at 7.5 percent and 10 percent of the benchmark, respectively. We believe that these limits are too low and that it is in the agency's best interest to set this limit at a higher rate of 20 percent of the ACO's benchmark. We believe that a higher limit will incentivize ACOs to participate in the program and to engage in the types of care coordination and disease management programs that will result in greater savings to the organization and Medicare, resulting in a greater potential share of savings for the ACO over the term of the agreement.

Repayment of Losses (§ 425.5(d)(6))

Under either payment Track One or Track Two, ACOs are subject to a 25 percent withholding of their shared savings. CMS states in the rule that this is to help ensure repayment of any losses to the Medicare program. The Center recommends that CMS eliminate this

requirement in the final rule. We believe that there are sufficient other mechanisms in place to ensure that the agency is protected in the event of a loss. For example, ACOs are required to demonstrate that they have an adequate mechanism for repaying losses equal to at least one percent of the ACOs per capita expenditures for assigned beneficiaries, and ACOs are required to demonstrate a repayment mechanism prior to entering the two-sided model. In addition, we believe that this 25 percent withhold will serve a major deterrent from participation in the program.

State Regulation of Risk Bearing Organizations

In the MSSP proposed rule, CMS states that it did not intend for proposals to render states responsible for bearing the costs resulting from the oversight of the program, but the agency acknowledges that in certain instances, state regulation of risk oversight may be implicated. We believe that for ACOs that accept risk, there will need to be another layer of regulatory requirements and regulation of the organizations to ensure success. For example, we believe that reserve requirements will need to be established based on risk corridors and that state insurance commissioners will need to regulate such requirements. This additional layer of regulation has the potential to be burdensome on ACOs and CMS should keep such considerations in mind as it develops additional payment models for ACOs.

Patient centeredness (§ 425.5(d)(15))

The MSSP proposed rule sets forth specific requirements relating to patient centeredness criteria. Specifically, ACOs are required to demonstrate patient-centeredness by addressing a list of criteria, including having a beneficiary experience of care survey in place and describing how the ACO will use the results to improve care over time.

Patient-centeredness is one of the most important aspects of ACOs and we believe it will be determinative of their success. In our experience, focusing on patient-centered care has resulted in tremendous success for our patients and for our providers. For example, in 2008, using Lean principles, the ThedaCare Clinic in Kimberly, WI reduced waiting room time from 15-20 minutes to an average of 5 minutes. Further, tests that often took days were consistently provided within 15 minutes and resulted in time for the physician to include these results in the outpatient visit leading to nearly 100% of patients leaving the office with a complete plan of care requiring no further phone calls to the office or from the office to the home. The same Lean methodology turned the clinic from losing $400,000 a year into a profitable clinic. This was accomplished through activities such as creating a high-volume on site mini-lab, redesigning the patient flow to make sure that appropriate tests were available when the physician needed it, reducing needless motions such as a nurse wandering halls looking for supplies, and reducing unnecessary inventory.

There are no incentives established that lead to a better patient experience. The rule is meant to create more coordinated care but there is no measure for this coordination. Simple measures such as time to biopsy for an abnormal mammogram, for example, should be developed to determine if ACOs are delivering better care. Quality metrics should be focused on patient experience. A once a year CAHPs survey is a very weak indicator of the patient experience. In order to make these types of improvements in patient care, it is essential that ACOs have access to real-time Medicare data on their patient populations. The CAHPs Survey, proposed in the rule, provides only retrospective information and therefore does not provide the

necessary data to allow providers to correct their actions to address the patient experience. Although we recognize the importance of having standardized data and scoring for ACOs, real time data is required for ACO's to make improvements and achieve truly patient-centered care.

Our concern is that providers will simply get bigger to meet the ACO criteria rather than actually delivering better care. We have a simple 4 question survey that is provided at every patient visit where we get real time information on the patient experience and then improve it immediately if the care is not meeting patient expectations. CMS should suggest in the final rule that all providers develop their own real time data on the patient experience.

Data Sharing (§ 415.19)

The MSSP proposed rule would make certain data available to the ACO. Aggregate data would be available to the ACO at the start of the agreement period based on the historical beneficiaries used to calculate the benchmark and quarterly during the agreement period. In addition, ACOs may request certain data, including beneficiary names, date of birth, and health insurance claim number. Beneficiary identifiable data would be available to ACOs upon their request for certain purposes. However, beneficiaries will have the opportunity to opt-out of having their claims data shared with the ACO.

The Center encourages CMS to reconsider these proposed data sharing requirements. We believe that providers need more complete and timely data in order to make the care improvements the agency is seeking. For example, in the PHPR pilots, the workgroups that developed the pilots ensured that the providers would have access to the claims data they need. The PHPR pilots implement the data feedback loop through requirements on both the provider and payer ends of the arrangement. Providers are required to have and use electronic medical records. Payers are required to give participating providers clean, complete, thorough and accurate claims data. Pilot-participating providers have access to quarterly data but can request data more frequently if they need it, for example on a monthly basis. In addition, many Wisconsin providers have the ability to access quality performance data through the Wisconsin Collaborative for Healthcare Quality database. We believe that this timely access to claims and quality data is a crucial component to a successful care delivery redesign program and so we encourage CMS to consider ways in which it can make more detailed, complete and timely data available to ACOs.

Encouraging Participation of Smaller Organizations

The Center is concerned that under the proposed structure of the MSSP, it will be incredibly difficult for smaller ACOs or physician-only ACOs to participate in the program. We believe that the regulatory burdens created by the rule in combination with the specifics of the financial components of the program will create insurmountable barriers for these smaller groups to participate in the program. As currently proposed, unless these organizations have a significant amount of capital, they will be unable to participate in the MSSP. If small ACOs are unable to form we believe that the ACO program may have the unintended effect of driving consolidation in the market, ultimately leading to higher costs, rather than lower costs. In addition, consolidation in the market results in fewer choices for patients, which is clearly an undesirable outcome. Therefore, the Center encourages CMS to consider the various ways in which small organizations and physician-only ACOs can be encouraged to participate in the program.

Continuing to Drive Delivery System Reforms through the Innovation Center

The CMMI recently announced a Pioneer ACO Model. According to the CMMI, the Pioneer ACO model is designed for those organizations and providers that are already experienced in coordinating care for patients across settings. Pioneer ACOS will move from shared savings to a population-based payment model and will work in coordination with Medicare, Medicaid, and commercial payers.

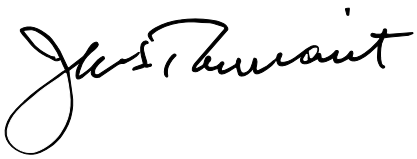
In its request for applications for the Pioneer program, CMMI describes shared learning activities for Pioneer ACOs. Specifically, the agency describes supporting Pioneer ACOs by providing them with opportunities to learn how care delivery organizations can achieve performance improvements quickly and effectively and opportunities to share their experiences with one another and other Innovation Center initiative participants.

The Center is uniquely qualified to provide a support function for the agency in connection with these objectives. As described above, we have experience with peer-to-peer network learning and we have broad-based experience in coordinating this type support function and shared learning experience for providers. We believe that we can provide valuable insights for the Pioneer ACO program and that we can assist in spreading the key elements of successful Pioneer ACOs to other providers in this and other CMMI initiatives.

Conclusion

We appreciate the opportunity to provide comments regarding the agency's implementation of ACOs. If you have any questions about the information provided above, please do not hesitate to contact us.

Sincerely,



John Toussaint