Received 7-30-14 MFPB

PETITION FOR AN ADJUSTED NEED DETERMINATION IN THE 2015 STATE MEDICAL FACILITIES PLAN

Petitioner:

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Requested Adjustment

Triangle Orthopaedic Associates, PA (TOA) requests inclusion of an adjusted need determination in the 2015 State Medical Facilities Plan (SMFP) for one Medicare-certified home health agency located in either Wake, Durham or Orange County (Triangle Area), committed to coordinating post-acute care with an orthopaedic surgery program. The agency shall be part of a demonstration project to facilitate the use of bundled payment for episode of care, and to maximize the potential for cost savings and quality outcomes for orthopaedic patients.

Background

TOA is the Triangle's largest physician-directed medical practice, caring for patients through state-of-the-art medical treatment, orthopaedic surgery, physical medicine and rehabilitation, rheumatology, general surgery, bariatrics, neurology, wound care, physical therapy, occupational (hand) therapy, and other medical and diagnostic services.

TOA is responsive to the needs of patients living within its service area of twelve North Carolina counties. TOA is committed to participating in efforts to improve quality care while also reducing healthcare expenditures. In fact, TOA is currently participating in two (2) separate demonstration projects pursuant to North Carolina State Medical Facility Plan (SMFP) adjusted need determinations: 1) the 2008 fixed multi-position MRI scanner demonstration project (HSA IV, V and VI), and 2) the 2010 single-specialty ambulatory surgery demonstration project (Triangle Area).

The requested special need determination and demonstration project is essential to facilitate participation in ongoing efforts by providers and payors to reduce overall healthcare expenditures and improve patient outcomes. The following narrative provides contextual information, historical utilization, cost data and the rationale justifying the requested adjustment.

Justification for the Adjusted Need Determination

TOA requests an adjusted need determination for one Medicare-certified home health agency to enhance quality of care, cost effectiveness and continuity of care experience. The petition request for an adjusted need determination is based on several factors:

- Demand for orthopaedic surgery has increased significantly in recent years due to changes in technology and demographics.
- TOA surgeons annually perform thousands of orthopaedic surgical procedures.
- Bundled payments are considered a useful method to change the way health care is delivered, both through optimization and engagement across the continuum of providers.
- Bundled payment is widely seen in the health care industry as an effective way to increase quality while reducing medical costs, particularly with orthopaedic surgical procedures.
- Implementation of bundled payment programs can result in significant cost savings in North Carolina.
- TOA currently participates in two bundled payment programs with Blue Cross Blue Shield of North Carolina (BCBSNC) to receive a bundled payment for knee replacement surgeries and hip replacement surgeries performed at the North Carolina Specialty Hospital in Durham. The agreement was the first bundled payment model in North Carolina between BCBSNC and a physician-owned practice.
- In 2015, TOA will likely begin bundled payment arrangements with the Centers for Medicare and Medicaid Services (CMS) for up to 15 episodes of orthopaedic surgical care.

- TOA refers hundreds of patients annually for post-acute home health services. This number is expected to increase as the local population continues to grow and age, and also with the growth of TOA physicians.
- Without the ability to directly provide post-acute home health services, orthopaedic providers such as TOA will continue to be limited in their ability to fully integrate and coordinate patient post-surgical home care with pre-surgical and surgical care.

Reasons Supporting Requested Adjustment

Bundled Payments

Health policy discussion during recent years has placed much attention on the adverse effects of fee-for-service payment, the principal method of paying for health care services in the United States. Fee-for-service payment has been widely criticized for financially motivating providers to focus on increasing volume of services, thereby contributing to the nation's high rate of health care cost growth. Fee-for-service payment has also been faulted for contributing to fragmented and sometimes harmful care[1].

Bundled payment is one alternative to fee-for-service payment. Bundled payment is widely seen in the health care industry as an effective way to increase quality while reducing medical costs, particularly with orthopaedic surgical procedures, such as the total knee replacement and hip replacement. Under these agreements, medical teams work together to reduce complications, prevent readmissions, and coordinate care.

Bundled payments are seen as a useful method to change the way health care is delivered today both through optimization and engagement across the continuum of providers. One of the goals of bundled payment programs is to break the fragmented, silo approach to care that currently exists.

In the last decade, there have been numerous bundled payment programs and demonstration projects between various payors and providers. The following highlights four well-publicized initiatives that brought widespread attention to the bundled payment strategy:

- In 2006, the PROMETHEUS Payment model was launched with the support of the Robert Wood Johnson Foundation through four initial pilots. PROMETHEUS now includes 21 bundles that can potentially impact payment for almost 30 percent of the insured adult population[2].

[1] Painter, Michael. Bundled Payment Across the U.S. Today: Status of Implementation and Operational Findings, Health Care Incentives Improvement Institute. April 2012

[2] PROMETHEUS Payment. What is PROMETHEUS Payment? An Evidence-Informed Model for Payment Reform. 2009, available at www.rwjf.org/qualityequality/product.jsp?id=43951.

- In 2007, Geisinger Health System began offering a bundled payment rate for Coronary artery bypass grafting (CABG) surgery, including preoperative evaluation and work-up, inpatient facility and physician services, routine post-operative care, and any required treatment of complications[3]. Geisinger also guaranteed adherence to a set of 40 clinical performance standards specific to the bundle. Geisinger subsequently added additional bundles.

- In 2009, the Centers for Medicare and Medicaid Services (CMS) implemented a bundled payment demonstration, titled the Acute Care Episode (ACE) Demonstration. This demonstration expanded upon the previous Heart Bypass Demonstration by including three joint replacement bundles and five cardiovascular procedure bundles. Five health systems were chosen for participation[4]. One health system has self-reported positive results.

  In 2011 Baptist Health System reported reducing spending by $4.3 million since the program's inception, or approximately $2,000 per case in the ACE demonstration. CMS also reduced costs through discounted bundled fees, and physicians added $280 in gain-sharing payments per episode[5].

- In 2011, CMS launched the Bundled Payments for Care Improvement Initiative (BPCI) under the authority of the Affordable Care Act. The initiative utilizes four different models:

  ◊ BCPI Model 1: Inpatient stay only (discounted IPPS payment);
  ◊ BCPI Model 2: Inpatient stay plus post-discharge services (retrospective comparison of target price and actual FFS payments);
  ◊ BCPI Model 3: Post-discharge services only (retrospective comparison of target price and actual FFS payments), and
  ◊ BCPI Model 4: Inpatient stay only (prospectively set payment)

All of the aforementioned activities, combined with a growing national consensus that movement away from fee-for-service payment is imperative in order to slow the growth of health care costs and to improve quality, have generated dozens of bundled payment programs. In fact, TOA was selected as a participant with Signature Medical Group in the CMS BPCI Model 2 program.

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[3] Lee TH. "Pay for Performance, Version 2.0?" The New England Journal of Medicine, Vol. 357, No. 6, August 9 2007, pp. 531-533.

[4] Medicare Acute Care Episode Demonstration or Orthopedic and Cardiovascular Surgery, available at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//ACE_web_page.pdf and Acute Care Episode Demonstration, available at www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads//ACEFactSheet.pdf.

[5] See The Health Industry Forum. "Episode Payment: Private Innovation and Opportunities for Medicare" Conference Report, Brandeis University, May 17, 2011, Washington, DC, available at http://healthforum.brandeis.edu/meetings/materials/2011-17-may/Final%20cr5-17-11.pdf.

BPCI Model 2: Retrospective Acute & Post-Acute Care Episode

Under the BPCI initiative, TOA and other organizations will enter into payment arrangements that include financial and performance accountability for episodes of care. The model is intended to lead to higher quality, more coordinated care at a lower cost to Medicare.

In Model 2, the episode of care will include the inpatient stay in the acute care hospital and all related services during the episode. The episode will end either 30, 60, or 90 days after hospital discharge. Participants can select up to 48 diagnosis related groups (DRG). There are 107 participants/awardees involved in the BPCI Model 2: Retrospective Acute & Post-Acute Care Episode. TOA will be participating in BPCI Model 2 through Signature Medical Group.

Effective January 1, 2015, TOA will likely enter into bundled payment arrangements for up to 15 episodes of orthopaedic surgical care. These include:

- Back & neck, except spinal fusion
- Cervical spinal fusion
- Combined anterior posterior spinal fusion
- Complex non-cervical spinal fusion
- Double joint replacement of the lower extremity
- Fractures of the femur and hip or pelvis
- Hip & femur procedures except major joint
- Lower extremity and humerus procedure except hip, foot, femur
- Major joint replacement of the lower extremity
- Major joint replacement of the upper extremity
- Medical non-infectious orthopedic
- Other knee procedures
- Removal of orthopedic devices
- Revision of the hip or knee
- Spinal fusion (non-cervical)

Research has shown that bundled payments can align incentives for providers – hospitals, post-acute care providers, doctors, and other practitioners – to partner closely across all specialties and settings that a patient may encounter, with an objective to improve the patient's experience of care during a hospital stay in an acute care hospital, and during post-discharge recovery.

TOA is an optimal participant for the BPCI Model 2 program. In addition to the numerous office locations dispersed throughout multiple counties in central and eastern North Carolina, TOA jointly owns the North Carolina Specialty Hospital located in Durham. This privately owned medical facility provides individualized attention to every patient it serves.

In 2009, North Carolina Specialty Hospital was named the top hospital in North Carolina, and among the top 10 in the United States, for its patient care ratings, per the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), a division of CMS.

TOA is excited to become part of the federal initiative that may fundamentally change the way healthcare is delivered, in a manner that reduces cost while improving outcomes. In fact, TOA has already begun participation in commercial bundled payment programs in North Carolina.

TOA-BCBSNC Bundled Payment Program

In 2012, TOA entered into an agreement with Blue Cross Blue Shield of North Carolina (BCBSNC) to receive a bundled payment for knee replacement surgeries performed at the North Carolina Specialty Hospital in Durham. BCBSNC has similar agreements that are place with other North Carolina hospitals; however, this agreement was the first bundled payment model in North Carolina between BCBSNC and a physician-owned practice. The payment model enables BCBSNC customers, including State Health Plan members, to pay a fixed price for knee replacement surgeries.

This new payment model secures a fixed fee that covers patients for the entire scope of knee replacement surgery, through physical therapy and for follow up care for 90 days after discharge. The innovative agreement between TOA and BCBSNC aims to reduce potentially avoidable complications, lower costs and improve patient outcomes on total knee replacement surgeries.

The TOA-BCBSNC Bundled Payment Program includes the following:

- All appointments and care occurring during the inpatient stay, including the total knee replacement, physical therapy and care related to any complications.
- All related outpatient care for 90 days after discharge, including home health care, ER visits, urgent care visits, physical therapy and follow-up physician visits.

The objective of the TOA-BCBSNC bundled payment program is to create communication channels within the care pathways that create continuous improvement in the delivery of orthopaedic surgery. The bundled payment program is intended to create a continuous feedback loop that streamlines quality of care.

BCBSNC chose knee replacement as the episode of care in its payment bundle program based on its opportunities to optimize care. Knee replacement surgery is the most common joint replacement procedure. According to the Agency for Healthcare Research and Quality, health care professionals perform more than 600,000 knee replacements annually in the United States[6].

Costs for knee replacement surgery frequently vary from provider to provider. The average cost for a 180-day episode of total knee replacement was $22,611 for Medicare patients and $25,872 for commercial patients[7].

[6] Lee, Jaimy. Bundled payments give surgeons a powerful new incentive to reduce costs. Modern Healthcare, March 1, 2014. http://www.modernhealthcare.com/article/20140301/MAGAZINE/303019981

[7] Rastogi et al. HCI3 IMPROVING INCENTIVES ISSUE BRIEF - ANALYSIS OF MEDICARE AND COMMERCIAL INSURER-PAID TOTAL KNEE REPLACEMENT REVEALS OPPORTUNITIES FOR COST REDUCTION

As the Triangle's largest physician-directed medical practice, TOA performs hundreds of knee replacement surgeries each year. The following table summarizes this recent utilization.

Triangle Orthopaedic Associates, PA
Knee Replacement Surgeries, CY2013-CY2014

Year	Knee Replacement Surgeries
CY2013	982
CY2014 (*Annualized**)	972

*Annualized based on six months data (Jan-June)
Source: TOA internal data

Based on 2013 data, BCBSNC customers have already benefited from the TOA bundled payment agreement. Overall results show:

- An average cost saving of more than 22 percent for knee replacement surgeries.
- Peer-based outcome measures that are trending better than national benchmarks.
- A reduction in potentially avoidable complications as compared to other total knee replacements performed in North Carolina.
- Patient satisfaction with the care team carries a 97 percent rating.

Due to the success of the knee-replacement program, BCBSNC and TOA expanded their efforts to provide better quality and cost options to patients through a coordinated care arrangement. In 2013, BCBSNC and TOA implemented the first bundled payment model for hip replacement surgeries in North Carolina. The cost of a hip replacement surgery and follow-up care in North Carolina can range from $22,000 to $52,000. The one-time payment in the bundled payment program is 10-20 percent less than the average cost of hip replacements in North Carolina. BCBSNC spokespersons have reported to media outlets that they saw this bundled payment system as the wave of the future in funding joint replacement[8].

BCBSNC spokespersons Elaine Daniels said that when they began paying a flat fee for knee replacements, they "*expected to see positive results with this. Instead, the results have been transformative*."

In TOA's experience, the bundled payment program has improved cost effectiveness, efficiencies and coordination between orthopaedic surgical services provided at the North

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http://www.hci3.org/content/hci3-improving-incentives-issue-brief-analysis-medicare-and-commercial-insurer-paid-total-kn

[8] http://ryortho.com/breaking/one-bill-joint-surgery-growing/

Carolina Specialty Hospital and outpatient services provided at TOA's physician clinics; however, patient care remains fragmented for many TOA patients who require post-acute home health services.

Fragmented Care & Need for Requested Adjustment

Under the TOA-BCBSNC bundled payment program, TOA is able to leverage its ownership stake in the North Carolina Specialty Hospital and its numerous TOA physician clinics to facilitate communication, coordination and follow up for pre-operative and operative patient care. However, some post-operative services remain fragmented. Specifically, home health remains disjointed from the continuum of care.

Independent physician practices, like TOA, are at a significant disadvantage when it comes to optimizing home health care for post-surgical patients. For example, TOA physicians receive little feedback regarding patient care for its patients' home health services. Some physicians refer to this gap as a "black hole" for information regarding post-acute patient care. This is especially problematic for TOA's participation in the TOA-BCBSNC bundled payment program because physical therapy is critical to post-operative recovery and occurs in the majority of orthopaedic surgical cases. This will be exacerbated when TOA soon begins participation in the CMS BPCI Model 2 program. As described previously, TOA will likely enter into bundled payment arrangements for up to 15 episodes of orthopaedic surgical care, most of which involve post-acute home health care.

In bundled payments, the healthcare provider (i.e. TOA) accepts the risk; thus, to manage that risk by providing more cost-effective care and improving quality, it is imperative to build in economies, standardize protocols, and create engaged ancillary services. In this case, TOA has engaged the acute care component with the North Carolina Specialty Hospital and some post-acute care via its existing office-based medical and physical therapy services; however, home health remains fragmented from the continuum of care.

The import of engaged post-acute home health services in the continuum of orthopaedic surgical care should not be marginalized. Surgeons may become unaware of potential avoidable complications or issues, like a secondary infection, in the post-acute phase of surgery. Lack of communication and or coordination between the orthopaedic surgeon and the post-acute provider can result in readmissions, which are suboptimal from patient care, quality and cost perspectives.

Hospital systems that operate owned or affiliated home health agencies (for example, Duke, Rex, and WakeMed) are already positioned to maximize their potential to reduce healthcare expenditures and improve outcomes. These organizations can leverage administrative overhead, IT infrastructure (e.g. electronic medical record systems), integrated care, standardized care protocols, staff training and quality improvement programs across service lines to increase the opportunity for improved outcomes. However, most independent physician practices, like TOA, are unable to take advantage of these economies and must attempt to overcome the hurdle of fragmentation in ancillary services such as home health care. This puts physician practices at a significant disadvantage in bundled payment programs compared to hospital systems.

TOA is unique in that it jointly owns one of the few specialty hospitals in North Carolina, and the only such hospital in the Triangle. TOA is also unique in that it participates in multiple bundled payment programs, each with the shared objectives of improving cost effectiveness and quality patient care. The requested adjustment for a home health agency is essential to facilitate the use of bundled payment for episode of care and to maximize the potential for cost savings and quality outcomes. Furthermore, the inclusion of the home health agency as part of a demonstration project will enable the Division of Health Service Regulation (DHSR) to measure and evaluate these objectives.

Regulatory Compliance

The proposed Medicare-certified Home Health Agency demonstration project will maintain compliance with all applicable regulatory, licensure, certification, and accreditation standards. The agency will be certified as a provider for the Title XVIII (Medicare) program and Title XIX (Medicaid) program, and will comply with Medicare rules and regulations (including Stark laws). The agency will also seek ACHC accreditation, and will operate the agency in compliance with state licensing requirements.

Demonstration Project Criteria

As described previously, TOA is currently participating in the 2010 single-specialty ambulatory surgery demonstration project (Triangle Area). As this requested SMFP adjustment is related to post-acute orthopaedic surgical care, TOA used the 2010 demonstration project criteria as a model for this requested adjustment and demonstration project. TOA developed the following criteria specific to the proposed adjustment, and to embody the basic principles of the State Medical Facilities Plan.

CRITERIA	CRITERIA BASIC PRINCIPLE & RATIONALE
Establish a special need determination in the for one Medicare-certified home health agency operated with an existing orthopaedic surgical program located in the following service area: • Wake, Durham, Orange County (Triangle)	*Value* The 3-county Triangle market has a current population exceeding 1.4 million, and hosts 20 Medicare-certified home health agencies. Locating the proposed service in high population areas with a large number of existing home health providers prevents the proposed agency from having a detrimental impact on a single existing provider, which can be disadvantageous in rural areas.
In choosing among competing demonstration project facilities, priority will be given to agencies that are owned wholly or in part by physicians.	*Value* Giving priority to demonstration project agencies owned wholly or in part by physicians is an innovative idea with the potential to improve

	safety, quality, access and value. Implementing this innovation through a demonstration project enables the State Health Coordinating Council to monitor and evaluate the innovation's impact.
Each demonstration project agency shall provide care to the indigent population. Demonstration project agencies shall report utilization and payment data to the statewide data processor. The Agency will review indigent care access submitted by the home health demonstration project agency.	*Access* Requiring service to indigent patients promotes equitable access to the services provided by the demonstration project agency.
Demonstration project agency will maintain compliance with all relevant licensure, certification, and accreditation standards. Demonstration project agencies shall submit annual reports to the Agency regarding the results of patient outcome measures. Examples of patient outcome measures include: • Beta blocker during preoperative period • Venous thromboembolism (VTE) prophylaxis • Length of stay • Readmission rates related to knee replacement as well as all-cause readmissions • Revisions within 90 days of discharge • Complications, including infection, deep vein thrombosis, pulmonary embolism within 30 days of discharge • Patient satisfaction • Functional outcomes measures (e.g. WOMAC, Knee Society Score, etc.)	*Safety & Quality* Implementing a mechanism for reporting safety and outcome measures promotes identification and correction of quality of care issues and overall improvement in the quality of care provided.
Demonstration project agency is encouraged to develop systems that will enhance communication and ease data collection, for example, electronic medical record.	*Safety & Quality, Access, Value* Electronic medical records improve the collection of quality and access to care data and collecting data is the first step in monitoring and improving quality of care and access.
Demonstration project agency shall obtain a license and certification no later than one year from the date of issuance of the certificate of need.	*Access & Value* Timely project completion increases access to services and enhances project value.

The petitioner values the collective wisdom of the North Carolina Medical Society and the Association for Home & Hospice Care of North Carolina and requests that the two organization work together to assist the demonstration project agency in developing quality measures and increasing access to the underserved.	*Safety & Quality, Access, Value* Collaboration between the North Carolina Medical Society and the Association for Home & Hospice Care of North Carolina and requests that the two organization in an effort to develop quality measures and increase access to the underserved promotes all three Basic Principles.
Demonstration project agency will provide annual reports to the Agency showing its compliance with the demonstration project criteria in the State Medical Facilities Plan. The Agency will evaluate the demonstration project agency for three years. If the Agency determines that the demonstration project agency is meeting or exceeding all criteria, the State Health Coordinating Council should consider allowing expansion of the demonstration project beyond the original proposed site, i.e. Triangle. If the Agency determines the demonstration project agency is not in compliance with any one of the demonstration project criteria, the Department, in accordance with G.S. 131E-190, "may bring an action in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized for injunctive relief, temporary or permanent, requiring the recipient, or its successor, to materially comply with the representations in its application. The Department may also bring an action in in Wake County Superior Court or the superior court of any county in which the certificate of need is to be utilized to enforce the provisions of this subsection and G.S. 131E-181-(b) and the rules adopted in accordance with this subsection and G.S. 131E-181(b)."	*Safety & Quality, Access, Value* Timely monitoring enables the Agency to determine if the demonstration project agency is meeting criteria and to take corrective action if the agency fails to meet criteria. This ensures that all three Basic Principles are met by the demonstration project agency.

TOA Home Health Patient Potential

TOA is the Triangle's largest physician-directed medical practice, caring for patients through state-of-the-art medical treatment, orthopaedic surgery, physical medicine and rehabilitation, rheumatology, general surgery, bariatrics, neurology, wound care, physical therapy, occupational (hand) therapy, and other medical and diagnostic services. TOA is comprised of over 50 physicians who perform thousands of surgical procedures each year. Each year, these surgical procedures result in hundreds of referrals for home health services. The following table summarizes recent utilization.

Triangle Orthopaedic Associates, PA
Home Health Referrals, CY2013-CY2014

Year	Home Health Referrals
CY2013	798
CY2014 (*Annualized**)	858

*Annualized based on six months data (Jan-June)
Source: TOA internal data

During CY2013, TOA referred 798 patients for post-acute home health services. This number is expected to increase over 7.5% in CY2014 based on year-to-date data. Referrals for post-acute home health services will continue to increase as the local population continues to grow and age, and also with the growth of TOA physicians. This volume is in excess of the 325 home health patient threshold and justifies the adjusted need petition for one additional Medicare-certified home health agency in the Triangle.

Potential Cost Savings

The opportunity to improve quality and lower health care costs through bundled payments and with the requested adjustment is significant. The following provides just one example, using total knee replacement surgery.

TOA Total Knee Replacement Surgery
Potential Annual Health Care Cost Savings
BCBSNC & Medicare Bundled Payment Programs

Column (A)	Column (B)	Column (C)	Column (D)	(B x C) x D
2013 TOA Total Knee Replacements	**BCBSNC & Medicare Total Knee Replacements**	**Average FFS Cost[9]**	**Potential Cost Reduction (%)**	**Potential Cost Savings ($$)**
982	767	$22,611	20%	$3,468,527

The table estimates significant potential cost savings for just one episode of care (knee replacement surgery). In 2015, TOA will likely enter into CMS bundled payment arrangements for up to 15 episodes of orthopaedic surgical care, most of which involve post-acute home health care. For the reasons previously described, the requested adjustment is necessary to fully maximize TOA's ability to improve quality and reduce health care expenditures.

Adverse Effects on the Population if no Adjustment to the Need Determination

This proposed demonstration project is innovative, and is consistent with the Basic Principles governing the development of the North Carolina SMFP. It is also completely responsive to the demands of the contemporary marketplace to reduce healthcare costs and to improve the quality of care. Therefore, adverse effects are associated with a scenario of not approving this proposed demonstration project.

Fee-for-service medicine is an antiquated model that no longer meets societal needs. Bundled payment plans are an example of the new care models that clearly represent the future of health care delivery. If the SHCC does not approve this petition, North Carolina citizens will lose a timely, real-world opportunity to improve the quality of total joint episodes of care and to increase the value of total joint care by reducing the overall cost of episodes of care. This would effectively stifle the full potential of innovations in orthopaedic healthcare delivery, at precisely

[9] Rastogi et al. HCI3 IMPROVING INCENTIVES ISSUE BRIEF - ANALYSIS OF MEDICARE AND COMMERCIAL INSURER-PAID TOTAL KNEE REPLACEMENT REVEALS OPPORTUNITIES FOR COST REDUCTION

the time when such innovation is necessary, and when CMS and other third-party payors (such as BCBSNC) are encouraging bundled payments and episodic treatment innovations.

As previously stated, an example is CMS's innovative new payment model, the Bundled Payments for Care Improvement initiative. Under the initiative, provider organizations enter into payment arrangements that include financial and performance accountability for episodes of care. CMS believes that these models are likely to lead to higher quality, more coordinated care at a lower cost to Medicare. Without access to directly providing post-surgical physical therapy home health, orthopaedic providers such as TOA will continue to be limited in their ability to fully integrate and coordinate patient post-surgical home care with pre & surgical care. This would result in a missed opportunity to maximize improvements in quality of care. Further, orthopaedic providers would also be limited in their ability to fully integrate and coordinate post-surgical home health care with pre & surgical care, thus missing an opportunity to maximize a reduction in the overall cost of the total joint replacement episode of care.

Alternatives to the Proposed Adjustment

This proposed adjusted need determination has few alternatives, none of which are feasible or attractive.

1. Status Quo. The status quo cannot continue in our country's healthcare industry. Society demands systemic innovation from healthcare providers, payors and regulators. Providers must reduce healthcare costs while simultaneously improving safety and quality, and these cost savings must occur now, not in the future. The current "silos of care" healthcare delivery model must be replaced with a more coordinated and integrative approach which focuses on the entire episode of care, which will offer better quality of care, lower costs, and a quicker path to achieving these necessary improvements.

2. Await a need determination for an additional Medicare-certified home health agency through the SMFP's standard home health services methodology. The 2014 SMFP determined no need in North Carolina for additional Medicare-certified home health agencies, nor does the Proposed 2015 SMFP include a need determination anywhere in North Carolina. Even if the SMFP included a standard need determination, a CON proposal for a Medicare-certified home health agency dedicated to orthopaedic treatment would be at a significant disadvantage in a competitive review, due to the higher volumes of patients contemplated by traditional applicants filing competing home health applications for broad-service home health agencies.

3. Acquire or partner with an existing Medicare-certified home health agency. This is not a realistic option because these agencies are rarely available for acquisition, and to TOA's knowledge, none are currently available within the Triangle marketplace. Further, the existing 20 Medicare-certified agencies in the Triangle marketplace are addressing the broad needs of home health patients, and, on average, are operating above practical capacity. Therefore, it would be counterproductive to decrease or limit the existing

approved home health capacity because it would reduce access to care for Triangle home health patients.

4. Wait for other states to demonstrate a successful integrated model. There is no question that this will happen: this petition has already described the innovative bundling models that are occurring right now throughout the United States. However, why should North Carolina's citizens, and particularly joint replacement patients, not be parties and beneficiaries right now to these important and innovative efforts?

5. Establish a statewide demonstration project. Although certainly preferable to the status quo, this alternative is not optimal because establishment of a demonstration project will be most effective if done in a growing metropolitan area with a concentrated population. The demonstration project needs volumes of patients with close, convenient access to total joint replacement care, including an orthopaedic surgical program. Further, the model is limited by the geographic service area definitions for licensed home health agencies.

No Unnecessary Duplication of Health Resources

This proposed demonstration project will not result in an unnecessary duplication of health resources because North Carolina has no specialized home health agencies directed by physicians and dedicated to coordinating post-surgical orthopaedic care with an orthopaedic surgery program.

The proposed agency will not serve a broad base of health specialties and thus will not broadly compete with existing home health agencies, but will focus on orthopaedics in order to facilitate the quality of care improvements and cost reductions that are expected by patients and third-party payors.

The 20 existing Durham, Orange and Wake County-based Medicare-certified home health agencies are operating at practical capacity. The Proposed 2015 SMFP shows that these agencies served a combined total of 16,458 patients during 2013, representing an average of 823 patients for each agency, which is higher than the SMFP threshold of 325.

Addition of this proposed Triangle-based Medicare-certified home health agency would modestly increase the Triangle agency inventory from 20 to 21, or just a 5% increase.

SMFP Basic Principles: Quality, Access & Value

Our state's economy no longer can support the cost of the care North Carolinians demand. Medicare and Medicaid are not sustainable at current levels, and employers cannot shift any more insurance costs to employees. Attempts at cost control such as preauthorization and

utilization review have failed because of the difficulty in second-guessing care decisions. This failure means that the providers of care need to have more incentives to control what care is delivered. Providers need to balance less care with appropriate care. The quality of care needs to be monitored, and best practices need to be adopted.

This requested adjusted need determination is consistent with the three Basic Principles governing the development of the SMFP: Safety and Quality, Access, and Value.

Safety & Quality

Approval of this petition will enhance the quality of healthcare services available to orthopaedic surgery patients. Physical therapy following orthopaedic surgery occurs in the majority of cases, and is critical to post-operative recovery. Patients will benefit from experienced orthopaedic surgeons who will directly oversee the complete spectrum of care for an orthopaedic surgery episode of care. This specialization and seamless coordination of care throughout the entire course of treatment will result in higher quality of care.

In addition, the proposed home health agency will be a Medicare-certified agency, and therefore will meet all state licensure requirements, and the Medicare conditions of participation.

Access

If this petition is approved, access to post-surgical health care for patients will be greatly improved. Triangle area residents will have access to post-surgical home healthcare that is coordinated with a high quality orthopaedic surgery program. The proposed home health demonstration project will accept Medicare and Medicaid patients as well as private pay patients. For information purposes, TOA's current payor mix for is approximately 27% for Medicare and approximately 6% for Medicaid. The proposed home health demonstration project would also provide access for medically underserved. TOA has charity care policies that enable access for medically indigent patients.

Value

As described in the Value Basic Principle of the SMFP, disparity between demand growth and funding constraints for health care services increases the need for affordability and value in health services. Fee-for-service payment has been widely criticized for financially motivating providers to focus on increasing volume of services, and thereby contributing to the nation's high rate of health care cost growth. Bundled payment is seen in the health care industry as an effective way to increase quality while reducing medical costs, particularly with joint replacements procedures. As previously described in this petition, cost savings have been shown with the bundled payment model, and can be maximized for the entire episode of care with a dedicated home health agency that is integrated with the attending surgeon.

In summary, TOA has identified a cost effective solution for advancing improvements in quality of care and cost effectiveness for orthopaedic surgery cases. Via the proposed orthopaedic home health agency that directs post-surgical home health care, the orthopaedic provider will be able to

fully integrate and coordinate patient post-surgical home care with pre & surgical care. The agency will also enable a provider to maximize a reduction in the overall cost of the total joint replacement episode of care. The proposed demonstration project will not negatively impact local residents seeking non-total orthopaedic care services as there will continue to be access to home health services via the 20 existing Medicare-certified agencies in the Triangle. Approval of this petition will greatly benefit patients in terms of access, quality and value.

Conclusion

TOA seeks to continue to encourage and lead innovative approaches to healthcare, with the objectives of improving safety and quality of care, reducing costs, and maintaining or increasing access to care. TOA requests an adjusted need determination for one Medicare-certified home health agency located in Wake, Durham or Orange counties in the 2015 SMFP. This petition has identified various special and unique circumstances that necessitate the development of this demonstration project. Furthermore, TOA has demonstrated that the request and proposed project are consistent with the Basic Principles of the State health planning process.

The SHCC historically has approved demonstration projects to model innovative approaches to achieve the basic principles of the SMFP. Demonstration projects enable healthcare providers an opportunity to offer for review useful solutions and data, under the monitoring and guidance of regulatory control. This demonstration project meets a contemporary need and provides a solution to a major societal challenge. Approval of this petition will result in improving patient access to higher quality, more cost effective episodes of care for orthopaedic surgery.

For these reasons, TOA respectfully requests that the Long-Term and Behavioral Health Committee and the State Health Coordinating Council include an adjusted need determination in the 2015 State Medical Facilities Plan (SMFP) for one Medicare-certified home health agency located in Wake, Durham or Orange counties, dedicated to coordinating post-surgical orthopaedic care with an orthopaedic surgery program.