

November 30, 2017

Physician-Focused Payment Model Technical Advisory Committee (PTAC)  
C/O Angela Tejada, ASPE  
Room 415F  
U.S. Department of Health and Human Services  
200 Independence Ave. S.W.  
Washington, D.C. 20201

*Via Electronic Submission:* [PTAC@hhs.gov](mailto:PTAC@hhs.gov)

**Re:** CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients

Dear Members of the PTAC

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments on a recently proposed Physician-Focused Payment Model (PFPM) to measure the effectiveness of physical or occupational therapy interventions as the primary means of managing wounds in Medicare recipients.

ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 94 percent of all American Board of Plastic Surgery board-certified plastic surgeons in the United States. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer reconstruction. ASPS promotes the highest quality patient care and professional and ethical standards and supports education, research, and public service activities of plastic surgeons.

Below we highlight several areas of concern with this proposal as written.

### **Appropriateness of Skin Substitutes**

As written, this model appears to limit beneficiary access to skin substitutes within the range of codes C5271-C5278 and Q4100-Q4172, and assumes low-cost skin substitutes are the most appropriate option for all wounds. However, ASPS believes that depending on clinical characteristics and circumstances, a high-cost skin substitute may provide greater overall value to the beneficiary and the Medicare program. Specifically, high-cost skin substitutes may increase dressing wear time, require less changing and associated medical supplies and visits, improve patient compliance, and ultimately reduce healing time and increase patient satisfaction. Further, many of these products have increased shelf-life, making purchasing and planning less stressful.

By both arbitrarily limiting the available options for skin substitutes while relying upon medical professionals who lack the appropriate training and expertise to ascertain which skin substitute would be most appropriate for beneficiaries, the model is fundamentally flawed and will likely result in poor patient outcomes.

### **PT/OT as “Primary Coordinator” of Chronic Wound Care**

As an indispensable professional in the overall treatment of chronic wound care, we disagree with the fundamental premise of the proposed payment model that physical therapists and occupational therapists (PT/OTs) are the appropriate “primary coordinator” of chronic wound care.

First, the submitters acknowledge key skills required to provide appropriate wound care, highlighting *sharp debridement* as chief among their skill set. Sharp debridement, even *conservative*, is an invasive procedure that does not fall within the scope of practice for PT/OT in all states. We do not believe the agency should establish a model that would unintentionally expand scope of practice for PT/OTs in the Medicare program.

Second, while PT/OTs have acquired the necessary training to perform certain services integral to wound care management, they do not possess the requisite expertise in diagnosis, management, and surgical technique required to treat wounds, especially chronic wounds. For example, the training of a PT/OT does not include the pathology of disease, which is fundamental given the impact diabetes, renal failure, peripheral vascular disease, and other risk factors (such as smoking) can have on wound healing. The submitters appropriately cite wound research, pointing to studies that demonstrate the challenge in wound healing for those patients with chronic, comorbid conditions. However, they failed to acknowledge other mitigating factors that play a role in clinical wound care, such as medications, offloading, nutrition, and tissue perfusion/oxygenation. Clinical decision making is key to getting chronic wounds to heal. Without understanding the pathophysiology of wounds and not addressing underlying contributing factors such as assessing whether there is adequate vascular flow/perfusion, off-loading, nutrition, adequate debridement/dressings, etc, the effectiveness of care decreases, increasing cost and patient morbidity.

Finally, PT/OTs are not equipped to address problems that may arise from the application of skin substitutes, such as the initiation of an immune response leading to rejection. For these reasons, PT/OTs are ill-suited as the “primary coordinator” of wound care.

While PT/OTs are *invaluable* members of the wound care team, ***we oppose a model that positions these professionals at the forefront of clinical decision-making for wound care.***

### **Measuring Quality of Care**

Notwithstanding our aforementioned concern, we note that the model does not include measures of *clinical* quality improvement, which are key to evaluating the impact on quality in relation to cost in any alternative payment model. The US Wound Registry, a Centers for Medicare and Medicaid Services (CMS) Qualified Clinical Data Registry (QCQR), includes several clinical quality measures relevant to

wound care, including measures of patient experience. Several of these measures have been developed in collaboration with the Alliance for Wound Care Stakeholders, which includes the American Physical Therapy Association (APTA). Despite being statutorily excluded from the Merit-Based Incentive Payment System (MIPS) until at least the 2019 performance year, the US Wound Registry will allow participation and reporting of clinical quality data by PT/OT. Bearing that in mind, we question how clinical quality will be measured if not through the registry. Given our obvious concerns with the model drastically affecting patient outcomes, it is critical that clinically relevant quality improvement be appropriately measured.

The submitter also states that the model would capture patient satisfaction. Unfortunately, the instrument planned for use is not described. While extremely important in measuring quality, patient satisfaction is highly subjective and requires the use of a valid, reliable tool. Surveys available under the Consumer Assessment of Healthcare Providers and Systems (CAHPS), generally regarded as the industry standard for assessing patient experience, do not include instruments appropriate for evaluating PT/OT care.

### **Conclusion**

We appreciate the effort made by Benchmark Rehabilitation Partners in fostering the development of a Physician-Focused Payment Model (PFPM) proposal. Nonetheless, we have significant concerns with the model as proposed, which would: 1) limit access to currently available advanced high-cost skin substitutes as well as potentially new, innovative skin substitutes that may be classified as high-cost; 2) inappropriately expand scope of practice for PT/OT; and 3) prioritize cost of care to the detriment of clinical quality.

### **We urge PTAC not to recommend the model for adoption and testing.**

Should you have any questions about our comments, please contact Catherine French, ASPS Health Policy Director, at [cfrench@plasticsurgery.org](mailto:cfrench@plasticsurgery.org) or at (847)981.5401.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey E. Janis". The signature is fluid and cursive, with a large initial "J" and "E".

Jeffrey E. Janis, MD, FACS  
President, American Society of Plastic Surgeons

cc: Lynn Jeffers, MD – ASPS Board Vice President of Health Policy & Advocacy  
Gayle Gordillo, MD – ASPS Board Vice President of Research  
Steve Bonawitz, MD – Chair, ASPS Healthcare Delivery Subcommittee  
Aamir Siddiqui, MD – Chair, ASPS Quality and Performance Measurement Committee  
Paul Weiss, MD – Chair, ASPS Coding and Payment Policy Subcommittee

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Physician-Focused Payment Model Technical Advisory Committee  
c/o U.S. Department of Health and Human Services  
Assistant Secretary for Planning and Evaluation, Office of Health Policy  
200 Independence Avenue, SW  
Washington, DC 20201  
Submitted electronically via [PTAC@hhs.gov](mailto:PTAC@hhs.gov)

**RE: Letter of Opposition to BenchMark Rehab Partners Physician-Focused Payment Model (PFPM) Proposal for CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy (PT/OT) Intervention as the Primary Means of Managing Wounds in Medicare Recipients**

Dear Members of the Committee:

MiMedx® Group Inc., is the leading biopharmaceutical company developing and marketing regenerative and therapeutic biologics utilizing human placental tissue allografts with patent-protected processes for multiple sectors of healthcare, including wound care. As the manufacturer of EpiFix®, AmnioFix®, and other products, we appreciate the opportunity to provide our perspective.

**PT/OT as “Primary Coordinator” of Chronic Wound Care**

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First, the submitters acknowledge key skills required to provide appropriate wound care, highlighting *sharp debridement* as chief among their skill set. Sharp debridement, even *conservative*, is an invasive procedure that does not fall within the scope of practice for PT/OT in all states. We do not believe the agency should establish a model that would potentially expand scope of practice for PT/OTs in the Medicare program for wound care.

Second, while PT/OTs have acquired the necessary training to perform certain services integral to wound care management, they do not possess the requisite expertise in diagnosis, management, and surgical technique required to treat wounds, especially chronic wounds. For example, the training of a PT/OT does not include the pathology of disease, which is fundamental given the impact diabetes, renal failure, peripheral vascular disease, and other risk factors (such as smoking) can have on wound healing. The submitters appropriately cite wound research, pointing to studies that demonstrate the challenge in wound healing for those patients with chronic, comorbid conditions. However, they failed to acknowledge other mitigating factors that play a role in clinical wound care, such as medications, offloading,

nutrition, and tissue perfusion/oxygenation. Finally, PT/OTs are not equipped to address serious complications that may arise, such as infection. For all of these reasons, PT/OTs are ill-suited as the “primary coordinator” of wound care.

***We oppose a model that positions these professionals at the forefront of clinical decision-making and the primary means of managing wound care.***

### **Appropriateness of Skin Substitutes**

The model limits beneficiary access to skin substitutes within the range of codes C5271-C5278 and Q4100-Q4172, assuming low-cost skin substitutes are the most appropriate option for all wounds. Depending on clinical characteristics and circumstances, a high-cost skin substitute may provide greater overall value to the beneficiary and the Medicare program. High-cost skin substitutes may increase dressing wear time, require less changing and associated medical supplies and visits, improve patient compliance, and ultimately reduce healing time and increase patient quality of life and patient satisfaction.

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### **Measuring Quality of Care**

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The submitter also states that the model would capture patient satisfaction. Unfortunately, the instrument planned for use is not described. While extremely important in measuring quality, patient satisfaction is highly subjective and requires the use of a valid, reliable tool. Surveys available under the Consumer Assessment of Healthcare Providers and Systems (CAHPS), generally regarded as the industry standard for assessing patient experience, do not include instruments appropriate for evaluating PT/OT care.

## **Conclusion**

We appreciate the effort made by Benchmark Rehabilitation Partners in fostering the development of a Physician-Focused Payment Model (PFPM) proposal. Nonetheless, we have significant concerns with the model as proposed, which would

- inappropriately expand scope of practice for PT/OT;
- limit access to currently available advanced high-cost skin substitutes as well as potentially new, innovative skin substitutes that may be classified as high-cost; and
- prioritize cost of care to the detriment of clinical quality.

**We urge PTAC not to recommend the model for adoption and testing.**

Sincerely,

A handwritten signature in black ink that reads "Laura T. Trivette". The signature is written in a cursive, flowing style.

Laura Trivette

*Vice President, Reimbursement and Health Policy*

Phone 770-651-9313

[ltrivette@mimedx.com](mailto:ltrivette@mimedx.com)

Via online submission to [PTAC@hhs.gov](mailto:PTAC@hhs.gov)

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Physician-Focused Payment Model Technical Advisory Committee  
Assistant Secretary of Planning and Evaluation, room 415F  
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**Re: CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients**

Dear Committee Members:

The American Occupational Therapy Association (AOTA) is the national professional association representing the interests of more than 213,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. The science-driven, evidence-based practice of occupational therapy enables people of all ages to live life to its fullest by promoting participation in daily occupations or activities. In so doing, growth, development and overall functional abilities are enhanced and the effects associated with illness, injuries, and disability, are minimized. We appreciate the opportunity to provide feedback on the “CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients” (hereinafter “the Model”) proposal for PTAC. AOTA supports the benefits associated with APMs that are intended to more efficiently and more effectively address the challenges affecting the Medicare population’s ability to access quality and effective wound care treatment and management in the appropriate setting.

I. Role of Occupational Therapy in Wound Management

AOTA appreciates the efforts of BenchMark Rehab Partners in proposing an alternative payment model that includes occupational therapy services in the care and treatment of wounds for Medicare beneficiaries. The prevention and amelioration of wounds to preserve and restore the ability of the individual to participate in meaningful, desired, and necessary daily life occupations is certainly a part of the occupational therapy scope of practice.<sup>1</sup> Further, the impact and costs of wound care evaluation and treatment to Medicare beneficiaries and the Medicare program are believed to be significant. In a study of 2014 data, nearly 15% of

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<sup>1</sup> The American Occupation Therapy Association. (2013). The Role of Occupational Therapy in Wound Management. *American Journal of Occupational Therapy*, 67 (Suppl. 6), S60-S68. <https://doi:10.5014/ajot.2013.67S60>

Medicare beneficiaries (8.2 million) had at least one type of wound or infection.<sup>2</sup> The study concludes that Medicare expenditures related to wound care are far greater than previously recognized, with care occurring largely in outpatient settings. The authors of the study suggest that the data could be used to develop more appropriate quality measures and reimbursement models, which are needed for better health outcomes and smarter spending for this growing population.<sup>3</sup>

The profession of occupational therapy not only treats the wound itself and evaluates wound healing and improvement, but occupational therapy practitioners also address the overall functional status as it relates to Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs), and medically necessary adaptations or modifications that impact the patient's ability to function independently in the community while participating in ongoing outpatient wound care treatment.

The AOTA position paper titled "*The Role of Occupational Therapy in Wound Management*," emphasizes that wounds and related conditions can limit a person's ability to fully participate in all daily activities including but not limited to performing self-care, work, social participation, rest and sleep.<sup>4</sup> As these limitations have both an effect on the physical and the psychological well-being of an individual and his/her quality of life, it is important that any future APM that addresses wound care also consider these aspects of health. Our position paper emphasizes that the occupational therapy perspective in this area combines an understanding of the mechanism and progression of acute and chronic wound healing and management, related body functions and structures, positive mental health, and the benefits of participation in everyday activities."<sup>5</sup> We are happy to provide any additional resources and education necessary in support of demonstrating occupational therapy's role in wound care for this proposal and, additionally, in an effort to ensure that future APM innovators have the information required to make an informed assessment on how to most effectively utilize occupational therapy services in their models.

## II. Feedback Regarding the Proposal

AOTA is pleased to see that the proposed model involves relevant standardized assessments for tracking functional outcomes of patients (such as the QuickDASH, LEFS, or Oswestry Disability Index), in addition to including peer reviewed assessments of the wound status alone (the Bates-Jensen Wound Assessment Tool). The inclusion of objective, standardized functional outcome measures is supported by AOTA and reflects best practice in implementing functional outcome scales at several steps of the process as part of the clinical approach. Further, the requirement for achieving a "minimal clinically important difference" (MCID) is best practice in the use of standardized instruments.

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<sup>2</sup> Samuel R. Nussbaum et al., An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds, *Value in Health*, (Sept. 2017) <http://dx.doi.org/10.1016/j.jval.2017.07.007>

<sup>3</sup> *Supra*, n.1

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at S61



AOTA also supports Benchmark Rehab Partners' efforts to further evidence quality outcomes through the criteria of (1) a demonstrable increase in functional independence as evidenced by the FIM or (2) a demonstrable progressive improvement in at least 2 objective measurements. The wound care practice financially risks refunding the cost of the service claims to CMS if these criteria are not met. While AOTA supports the use of objective and standardized measures as part of any APM model for wound care, we urge the PTAC to request that Benchmark Rehab Partners resubmit its proposal after taking the critical first step of collecting and sharing with the PTAC and stakeholders sufficient pilot data demonstrating how it has implemented the defined aspects of the proposal and achieved positive outcomes. AOTA believes that thoughtful and effective use of occupational therapy practitioners in innovative health delivery models can reduce the overall costs of Medicare services, reduce hospital readmissions and caregiver burden, while at the same time improve the outcomes achieved by beneficiaries. While this proposed model may indeed reduce Medicare cost and improve beneficiary outcomes, without data demonstrating the efficacy of the proposed model, AOTA is unable to assess the overall impact, including the degree of financial risk occupational therapy practitioners would need to undertake as key clinicians under this proposal.

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Thank you for the opportunity to comment on the CMS Support of Wound Care in Private Outpatient Therapy Clinics: Measuring the Effectiveness of Physical or Occupational Therapy Intervention as the Primary Means of Managing Wounds in Medicare Recipients proposal for PTAC. AOTA looks forward to a continuing dialogue with CMS and external health care entities on APMs that are intended to more efficiently and more effectively improve quality and cost outcomes for wound care management Medicare beneficiaries.

Sincerely,



Sharmila Sandhu, JD  
Counsel and Director of Regulatory Affairs



Ashley Delosh, JD  
Regulatory Analyst