AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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January 2 2019

Physician-Focused Payment Model Technical Advisory Committee (PTAC)
C/O Angela Tejeda, 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

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 the recent update to a previous proposal for a 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 93 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.

While we appreciate the work the submitters have taken to respond to questions previously posed, we continue to have concern with this updated proposal.

PT/OT as "Primary Coordinator" of Chronic Wound Care

We appreciate the submitters inclusion of a new requirement to communicate with the primary care provider more frequently (after first visit, after every 10th visit or every thirty days, whichever is sooner), but as an indispensable professional in the overall treatment of chronic wound care, we continue to disagree with the fundamental premise of the proposed payment model - physical therapists and occupational therapists (PT/OTs) should not be the "primary coordinator" of chronic wound care.

As noted in our previous comment letter, 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.

Additionaly, 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 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 chronic wound care***.

Focus of the Model

Chronic, non-healing wounds are defined as wounds that fail to proceed through the normal phases of wound healing in an orderly and timely manner. While we concur that chronic wounds are a challenge to wound care professionals and can consume a great deal of healthcare resources, we are disappointed to see this proposal places a stronger emphasis on the "functional" goals of physical and occupational therapy and fails to address the healing of a chronic wound as a primary indicator of success.

As an example, foot ulcers are often the result of shoe pressure, repetitive plantar stress or injury. If only focusing on functional goals such as ambulation, range of motion, or strength, the therapist may inadvertently delay healing by not identifying the true cause of the ulcer. ASPS is concerned that the inclusion of an exception clause, which would exclude the report of an unhealed wound as a measure of patient satisfaction, will further limit the focus of healing. Additionally, while the Bates-Jensen Wound Assessment Tool (BWAT) has been included as an instrument to measure wound severity, this proposal does not include any mention of a desire to decrease the BWAT score as a tool to achieve wound healing.

Complexity of Patient Evaluations

This updated proposal introduces a grading system for patient complexity (low, moderate and high) but does not clearly delineate the differences between those levels. Lacking this information, it is impossible to ascertain if an increase in treatment episode costs can be justified.

List of Diagnoses to be Included in this Model

Appendix B of this proposal includes an extensive list of ICD-10-CM codes for services the submitters have identified as appropriate for a payment model focused on wound care management. To ensure the focus of this model is *chronic* wounds, ASPS encourages the submitters to edit the list, and delete those diagnosis codes that should not be included as a primary reason for care of chronic wounds.

Examples:

B35.0 – B35.9 Dermatophytosis

L20-L30 – Moisture associated dermatitis

L40.0 – L40.8 Psoriasis

R29.3 – Abnormal Posture

Submission and Verification timelines

As written, this model proposes quarterly reporting of outcomes. ASPS is concerned this type of reporting may contribute to wasteful spending, as CMS will need time to review, identify, validate, and notify outlier providers. As indicated in Table 1, the verification process, as currently proposed would appear to allow underperformers to continue to participate for almost 15 months before termination from the program.

Table 1 – Verification Timeline

Quarter 1	**Patients seen.**	Data submitted at end of quarter
Quarter 2	New patients seen & existing patients continue to be seen.	CMS analyzes data & sends notifications to underperformers
Quarter 3	New patients seen & existing patients continue to be seen.	Underperformer has 1 quarter to improve score. CMS analyzes data & sends notifications to underperformers
Quarter 4	New patients seen & existing patients continue to be seen.	CMS analyzes data & sends notifications to underperformers and/or notification of termination from the program
Quarter 5	**Provider is terminated**	

As such, ASPS respectfully suggests the submitters consider an alternative, real-time reporting mechanism.

Appropriateness of Skin Substitutes

As discussed in our previous comments, ASPS believes that any payment model that limits 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 is fundamentally flawed and will likely result in poor patient outcomes and increased costs.

Conclusion

We appreciate the effort made by Upstream Rehabilitation in fostering the development of a Physician-Focused Payment Model (PFPM) proposal. Nonetheless, we have significant concerns with the model as proposed and **urge PTAC not to recommend the model for adoption or limited testing.**

Should you have any questions about our comments, please contact Catherine French, ASPS Health Policy Director, at cfrench@plasticsurgery.org or at 847.981.5401.

Sincerely,

Alan Matarasso, MD, FACS
President, American Society of Plastic Surgeons

cc: Greg Greco, MD – ASPS Board Vice President of Health Policy & Advocacy
Michelle Manahan, Chair, ASPS Health Policy Committee
John Ver Halen, MD – Chair, ASPS Healthcare Delivery Subcommittee
Paul Weiss, MD – Chair, ASPS Coding and Payment Policy Subcommittee

Via online submission to PTAC@hhs.gov

January 3, 2019

Physician-Focused Payment Model Technical Advisory Committee
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200 Independence Avenue, SW
Washington, D.C. 20201

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. [1] 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 Medicare beneficiaries (8.2 million) had at least one type of wound or infection.[2] The study

[1] The American Occupation Therapy Association. (2018). The Role of Occupational Therapy in Wound Management. *American Journal of Occupational Therapy*, 72 (Suppl. 2) 7212410057. https://doi.org/10.5014/ajot.2018.72S212.

[2] 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

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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.[3]

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 2018 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.[4] 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."[5] 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, in addition to the Bates-Jensen Wound Assessment Tool (BWAT and Patient Satisfaction), the proposed model involves relevant standardized assessments for tracking functional outcomes of patients (such as the QuickDASH, LEFS, Pain Scale and Oswestry Disability Index). 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. At the same time, AOTA agrees with the Model's request for certain MCID exemptions based on the fact that patients can achieve functional improvements that allow them to live independently but may not be picked up by outcomes measures (for example, the ability for a patient to perform toilet hygiene independently significantly improves their functional independence, but because individual toilet hygiene assessment items are not asked on the DASH, they might not achieve MCID on that measure).

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[3] *Supra,* n.1
[4] *Id.*
[5] *Id.* at S61

AOTA notes that one of the barriers preventing an equitable comparison of care between hospital-based outpatient clinics and free-standing private outpatient clinics, which is noted in the proposal, has been decreased by the passage of the Bipartisan Budget Act of 2018 (BBA18). BBA18 effectively repealed the outpatient cap on therapy services beginning in February 2018. While the KX modifier is still required on claims at or above $2,040 in 2019 for record-keeping purposes, CMS will permit Medicare beneficiaries to receive medically necessary therapy services above that dollar amount.

AOTA also supports Benchmark Rehab Partners' efforts to demonstrate quality outcomes by requiring (1) a demonstrable increase in functional independence as evidenced by the FIM or (2) a demonstrable progressive improvement in at least 2 objective measurements. 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.

* * *

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 PTAC, CMMI and CMS 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

January 1, 2019

Physician Focused Payment Model Technical Advisory Committee (PTAC)
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RE: Letter of Support for *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*.

With pleasure, the MiMedx Group, Inc. communicates our support of the accompanying alternative payment model proposed in the study. We agree with the purpose of the alternative payment model: to demonstrate how investment and support of outpatient therapy clinics to provide chronic wound care services to Medicare recipients will result in improved communication between members of the patient's healthcare team, to lower costs to provide care, and to show greater functional outcomes for the patient that extend beyond simple healing of the wound.

We also look forward to attending the March 11-12 public PTAC meeting in Washington, DC.

MiMedx submits a recommended change to the alternative payment model proposal:

- The current language proposes that "CMS will allow for the use and billing of advanced therapeutics, including skin substitutes and bioengineered dressings described in the codes C5271-C5278 and Q4100-Q4172" (p 6, 12, 16)
- **We suggest amending the proposal to also include procedure codes 15271 - 15278 as well as the full range of product codes Q4100 - Q4204**

The proposal, as is, does not take into account the HCPCs (product) coding changes that were implemented January 1, 2019. Amending the approved list to include products through Q4204 allows more patients to benefit from well-established products that received new codes this year, (such as EpiFix® and EpiCord ®) to be included in the study. Additionally, only using C5271 - C5278 as a procedure range precludes the use of many well-established products that are assigned under the current Outpatient Prospective Payment System (OPPS) model as high cost skin substitutes, since reimbursement for these skin substitutes are triggered by codes 15271 - 15278. It should be noted that the "high cost" designation is based on a per-unit cost, and does not necessarily translate to a higher cost per episode of care. Sometimes the episode of care cost with these products is less--due to improved results, improved efficacy and faster healing times. Since the proposal supposes reimbursement under the OPPS model, in order to best reflect the intent of the OPPS model it is important to capture both the 15271 - 15278 codes along with the C5271 - C5278 codes.

We submit that our suggestion is in line with the spirit of the proposal, that is, is to allow clinicians more options within the episode of care and to return the patient to functionality quickly. The proposal notes

a deficit in current treatment options with regard to dressings stating that: “No supplies would be paid for by Medicare, so the therapist will utilize the most cost-efficient, though not necessarily the most effective, dressings to manage the wound.” (page 24, treatment example 2). In the same way, excluding 15271 - 15278 codes and omitting the full range of product codes, limits many beneficial healing options for patients and effectively makes the current proposal replicate the very same deficits that the current system does for dressings. The proposal limits the advanced therapies it proposes to study; consequently, clinicians will use only low-cost skin substitutes under OPPS. These low-cost products may not be most effective, and therefore, may not be the most cost-effective across the episode of care.

Remember over time the costliest wound care related expenses are the ones that do not work be it products or processes. The creation of a system that improves access to effective wound healing tools for front line wound care providers is a project worth backing. Over the past decade MiMedx has been an innovative front-runner in the development of advanced wound care solutions that have helped a myriad of individuals heal chronic wounds. Despite the availability of these advanced wound healing technologies, more than 80,000 amputations are performed on diabetic patients in the United States each year.[1] Ulcers precede 85% of lower extremity amputations in persons with diabetes, and it is estimated that up to 85% of these amputations may be preventable.[2] In 2014, approximately 14.5% of Medicare beneficiaries were diagnosed with at least 1 type of wound or wound infection. This 14.5% represented approximately 8.2 million patients. Total Medicare spending estimates based on 2014 Medicare data for all wound types ranged from $28.1 to $96.8 billion.[3]

At present, there are over 1000 outpatient wound centers in operation in the United States. This is not inclusive of all the wound care rendered by clinicians in their offices, by inpatient acute care hospitals, and by long-term facilities and nursing homes.[4] Despite these numbers, individuals suffering from chronic wounds struggle with the issue of lack of access to a clinician who is knowledgeable in wound care. Compounding road blocks to wound care access range from the limited number of locations offering wound care services, geographic location of the patient, inhibitory cost of care and unreliable transportation. Most hospital affiliated wound clinics function at capacity and have at least a two to four week waiting period before assigning a first appointment. This extended waiting period before an initial evaluation places the patient with a chronic diabetic foot ulcer (DFU) at increased risk for a complicating infection. Diabetic foot ulcers persisting for a duration >30 days are 4.7 times more likely to become infected than an acute DFU. In fact, for diabetics with an ulcer who develop a foot infection, compared with those who do not, the risk of hospitalization is estimated to be 55.7 times greater (95% CI 30.3–102.2; $P < 0.001$) and the risk of amputation is 154.5 times greater (58.5– 468.5; $P < 0.001$).[5]

A logical next step in mitigating the medical and economic burden of chronic wounds on the Centers for Medicare & Medicaid Services is to expand access, especially in rural regions, to clinicians knowledgeable in wound care. In addition, a high priority for the proposed alternative payment model study should be to improve the relationship and communications between specializing wound care physicians and physical or occupational wound therapists. With today’s available, secure and affordable telehealth technologies physical or occupational wound therapists can conveniently contact specializing wound care physicians, along with the primary care physician, to determine if a stalled wound may need further sharp excisional debridement, which is out of the scope of practice of the majority of physical or occupational wound therapists.

There is level 1 evidence demonstrating DFUs that are targeted for skin substitute therapy, or more specifically, to be treated with dehydrated human amnion chorion membrane (dHACM) allografts are

71% less likely to heal within 12 weeks when the ulcers are inadequately debrided.[6] If wounds have evidence of delayed closure, < 50% reduction in the wound area over 4 weeks[7], then physical or occupational wound therapists should be permitted to apply and bill for advanced therapeutics that have level 1 evidence in improving the trajectory of wound closure, including skin substitutes and bioengineered dressings described in the codes C5271 - C5278, 15271-15278 and Q4100 - Q4204 for the patients identified in this study.

A primary goal of wound care is to close a chronic wound as quickly as possible since closure reduces long-term costs, but moreover it is better for the patient and reduces mortality that is associated with the complicating infections, hospitalizations and amputations.

For the foregoing reasons, MiMedx respectfully requests that the current proposal be amended to include procedure codes 15271 – 15278 and product codes Q4100 – Q4204 to improve patient health often at lower costs.

Sincerely,

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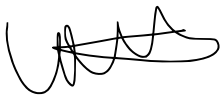

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