December 30, 2024
Partnership for Quality Measurement Pre-Rulemaking Measure Review Committee
Submitted Electronically via https://p4qm.org/media/3166
Re: MUC2024-100 Non-Pressure Ulcers Episode-Based Cost Measure Pre-Rulemaking Measure

Dear Partnerships for Quality Measurement (PQM; Powered by Battelle) and Centers for Medicare and Medicaid Services (CMS) Pre-Rulemaking Measure Review Committee:

I served as a member of the Clinician Expert Workgroup and as the representative of the Alliance of Wound Care Stakeholders. Since the Alliance has submitted separate comments, I will focus on the concerns raised by my own Field Test. I fully support the development of a measure which would reflect the cost of the care for non-pressure ulcers for costs that are clearly under the control of the practitioner. As a wound care practitioner, **I am providing examples from my own Field Test to demonstrate why the non-pressure ulcer cost measure currently under consideration should not be implemented.**

Although I was originally board certified in Family Practice (FP), for 34 years I have practiced only wound care. Since wound care is not a recognized medical specialty, and since I often provide the plurality of care for my patients in a given calendar year, in 2016, I was deeply concerned after reading my "QRUR" report which showed that hospitalizations for heart failure among my wound care patients were being attributed to my TIN. Since nearly 40% of my patients with chronic ulcerations have heart failure as a comorbid condition, and since these patients are often hospitalized for CHF exacerbations, CMS was mistakenly attributing these costs to me and there was no mechanism by which I could correct this. My costs were dramatically higher than my peers in FP and thus, in 2016, I achieved 3 out of 10 points for the cost measure applied to me, calculated among patients whose healthcare costs I had no part in determining. **As a result, I understand the need for a cost measure focused on non-pressure ulcers.**

Below are the concerns I raised with the Acumen team based on my Field Test report. **None of the questions below were answered by the Acumen team. I am deeply concerned by the inability or unwillingness of the Acumen team to address the concerns raised by the Field Tests and to run another Field Test to demonstrate that they were corrected.**

How can the "National Average" Cost be different for different doctors?

Below is my Table 1 and Table 1 from another wound care practitioner. Why is the "national average" different? It must not be a "national" average, if so. Is it a national average calculated specific to a group, such as by specialty, or is it by risk group? My specialty designation is now Undersea and Hyperbaric Medicine. I hope at least that I am being compared to other UHM specialists rather than to other FPs (my primary specialty). These differences are not an issue that an individual doctor could know about without seeing the reports of one's colleagues.

Wound care is practiced by so many different specialties, and it does not seem useful to subdivide reports by primary specialty. If this measure was developed primarily for podiatrists, we should have been informed of that at the beginning. **Most podiatrists practice wound care *incidentally* since they also perform podiatric surgery. In contrast, most other specialists are practicing wound care full time. However, without a specialty code, you do not understand that those practitioners are focused only on wound management.**

Table 1: Your Field Testing Cost Measure Score

	Non-Pressure Ulcers Measure
Number of Episodes	59
Your Cost Measure Score (TIN-NPI)	$10,492
National Average Cost Measure Score	$7,702
Your Cost Measure Score Percentile (TIN-NPI)	76

Note: Refer to the Glossary, Table A1 for definitions of metrics

Table 1: Your Field Testing Cost Measure Score

	Non-Pressure Ulcers Measure
Number of Episodes	55
Your Cost Measure Score (TIN)	$6,591
National Average Cost Measure Score	$8,340
Your Cost Measure Score Percentile (TIN)	56

Note: Refer to the Glossary, Table A1 for definitions of metrics

Here is Table 3 from the same two doctors. The share of episodes must not be "national" here either since they are different.

Table 3: Service Use and Cost by Medicare Setting and Service Category

Medicare Setting and Service Category	Share of Episodes with ≥1 Service			Average Observed Cost of Services among Episodes with ≥ 1 Service		
	Your TIN	National Average	Your Risk Bracket	Your TIN	National Average	Your Risk Bracket
All Services	100.0%	100.0%	100.0%	$7,507	$8,202	$8,677
Hospital Inpatient Services	12.7%	34.7%	25.7%	$8,103	$7,709	$7,450
Inpatient Hospital	7.3%	25.0%	16.4%	$12,824	$12,777	$12,542
Amputations for Circulatory System Disorders	0.0%	11.4%	5.2%	$0	$20,094	$19,691

Table 3: Service Use and Cost by Medicare Setting and Service Category

Medicare Setting and Service Category	Share of Episodes with ≥1 Service			Average Observed Cost of Services among Episodes with ≥ 1 Service		
	Your TIN-NPI	National Average	Your Risk Bracket	Your TIN-NPI	National Average	Your Risk Bracket
All Services	100.0%	100.0%	100.0%	$10,382	$7,935	$8,707
Hospital Inpatient Services	16.9%	47.0%	35.6%	$3,714	$7,756	$7,549
Inpatient Hospital	6.8%	38.2%	26.7%	$7,636	$12,930	$12,615
Amputations for Circulatory System Disorders	0.0%	25.8%	14.9%	$0	$20,396	$20,619

How can the "National Average" for Amputations be different for different doctors?

In Table 3, the national average of "Amputations for Circulatory System disorders" is 11.4% but in my colleague's report it is 25%. How is that possible?

Who are these doctors outside my TIN?

I looked at Table 4: Top Clinicians Within and Outside Your TIN Contributing to Your Part B Physician/Supplier Episode Costs. This table lists 5 practitioners, and **I did not recognize the names of <u>any</u> of them. I have never referred to any of these physicians nor have they ever referred a patient to me. Yet, they have contributed the most to my episode costs. How is that possible? Most of them are not even in my geographic area. I am confident that whatever costs they are associated with were never under my "reasonable control."**

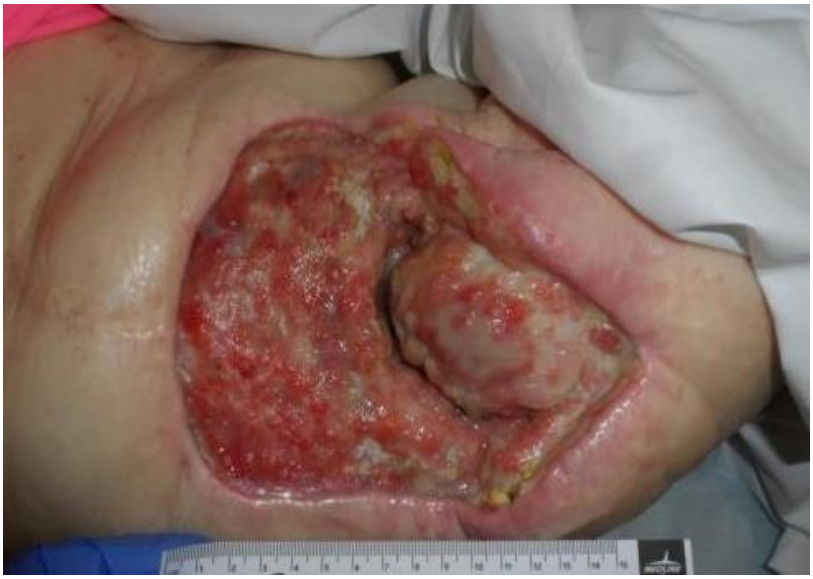
When I reviewed the associated Excel spreadsheet column W (NON_ATTR_NPI), of the approximately 53 physicians listed, I have had referral relationships with 9. The others I do not know. **Furthermore, some of the hospitalizations for patients occurred in cities distant from my own (including more than 100 miles away) and thus could not possibly be under my control. Indeed, I do not have admitting privileges at any of the hospitals listed.**

Of particular concern, Quest Diagnostic Laboratory is listed several times in column W, as if it is a "clinician", as is Southwest Regional Pcr LLC which is another laboratory. Why are laboratory services listed in column W, as if they are "Clinicians outside your TIN?"

There is a serious problem with attribution: Example -My most costly patient:

My most costly patient accrued a cost of $108,245.57. Using the date of birth, I looked up her medical records. My last visit with her occurred approximately 8 months before the end of the episode. Thus, **for more than 90% of her episode, I had no physician-patient relationship.**

My most costly patient had a large open wound to her right hip which exposed the hip joint following surgery for cutaneous calcinosis. She developed calcinosis as a result of high dose local radiation more than 40 years prior for a sarcoma. Long term survival of sarcoma patients is rare, and she underwent high dose radiation before fractionation. A year before seeing me, she underwent a wide excisional debridement of the irradiated field and then failed primary surgical closure in 2020. The photograph below shows her after she had improved dramatically. The photo depicts an open hip joint and the round structure on the right is the head of her femur. This chronic ulcer is more than 15 cm x 15 cm and extends into the pelvis.



She had planned on undergoing plastic surgical closure at a local hospital (arrangements not made by me or recommended by me). After deciding not to be followed by me anymore, she apparently became the patient of a nurse practitioner whose name I will not reveal in this letter. **I do not know that NP, but she is the top clinician contributing to "my" Part B costs.**

I looked up the NP and found that she is affiliated with a company which provides "mobile wound care" for the purpose of applying Cellular and/or tissue-based products (CTPs) in the home setting. As you can see, this massive wound would require many thousands of dollars of such products (inaccurately referred to as "skin substitutes") which are not recommended to be placed over bone or open joints.

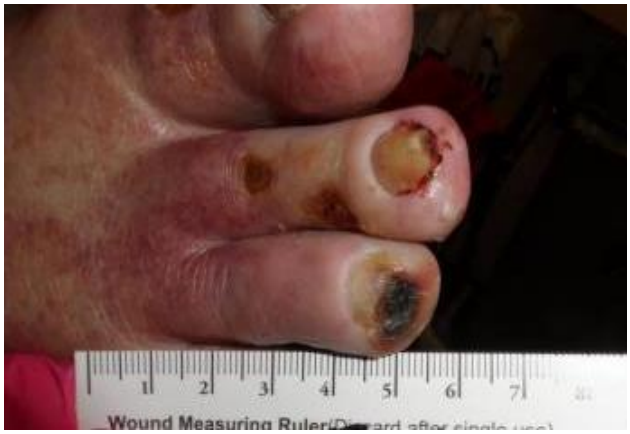
Here is what I have learned from this case:

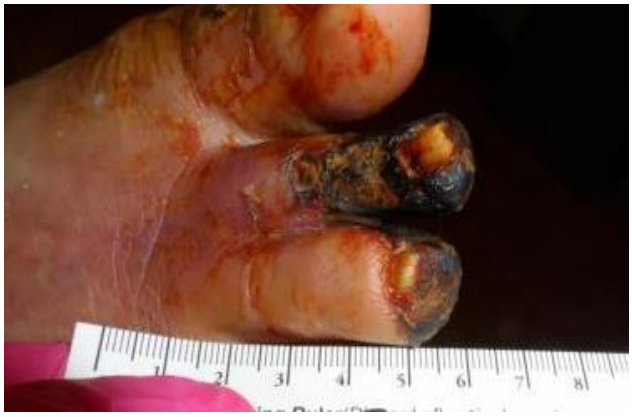
- **Costs have been attributed to me for services ordered by an NP who saw the patient after I was no longer caring for her.**
- **The charges provided by the NP who cared for the patient were excessive and highly questionable based on what I know about the patient but are nevertheless attributed to me.**
- **Calcinosis and late effects of radiation should be excluded from the cost measure.**
- **I need to know how "skin substitute" charges are being collected and allocated.**

There is a serious problem with attribution: Example-My second most costly patient

My second most costly patient accrued a cost of $74,367. I looked up this patient using his DOB. The patient had advancing necrosis of the toes on the right foot and increasing rest pain (despite diabetic neuropathy) in the setting of diabetes and chronic renal failure on dialysis. The ischemic changes of the foot had been getting worse for several months after a podiatrist nicked his toe when clipping his toenails. He had already undergone both surgical and endovascular revascularization, as well as surgery for a large abdominal aortic aneurysm and aortic valve replacement. He had previously been hospitalized at a skilled nursing facility for generalized weakness and repeated falls. Arterial screening performed in my office with skin perfusion pressure showed a flat pulse volume recording indicating that he had no capillary flow to the foot. His foot was cold, and his toes were ischemic. No further vascular interventions were possible. He was destined for a foot or leg amputation and the goal was to keep him as comfortable as possible, but he was not a candidate for hospice.

He had an ischemic foot on his initial visit. Photos below show the progression of the ischemia over a one-month period. He went on to amputation the following year.





Here is what I have learned from this case:

- **Patients with diabetes on dialysis and who are doomed to an amputation will create cost outliers. Failing to adequately account for this situation will make physicians reluctant to provide care to these unfortunate individuals.**
- **Costs are being attributed to me which are outside of my control.**

There is a serious problem with risk classification

Patient #2 above has the following comorbid conditions:

- Type 2 Diabetes
- Renal failure on dialysis
- Advanced peripheral arterial disease with gangrene
- primary hypertension
- iodine deficiency related thyroid disease
- heart failure
- peripheral neuropathy
- gastroesophageal reflux
- hyperlipidemia
- hypercholesterolemia
- major depression
- prostatic hypertrophy with urinary tract symptoms
- central sleep apnea
- anemia
- cerebrovascular disease

- history of falling
- aortic aneurysm
- ischemic heart disease status post coronary bypass
- right bundle branch block requiring a pacemaker
- malnutrition
- diabetic retinopathy
- obesity

His risk score is only 1.26. How is that possible?

It appears based on column H that my average risk score is 2. I am concerned that this is not reflective of the complexity of the patients we see. When I last looked at my CMS calculated HCC score, **my HCC score calculated by CMS was 3.24** and based on CMS data, my wound center patients had the following disease prevalence:

- Chronic kidney disease: 52.5%
- Diabetes: 47.8%
- Heart failure: 38.6%
- Ischemic Heart disease: 49.7%
- Atrial fibrillation: 19.9%
- COPD: 27%

The U.S. Wound Registry to which I contribute data shows that the average number of comorbid conditions among my patients is about 10 and they take 15 medications on average. I realize that the risk score created for this cost measure is not the same as the HCC score, but do not see how the risk could be as low as it appears to be in my spreadsheet.

Here is what I am concerned about:

- **There is a serious problem with the way that risk is determined, and a new method should be created (why does HCC not work)?**
- **I do not understand how individual patient risk will be taken into account for the cost calculations, even if I trusted that the risk was calculated fairly.**

There is a serious problem with the Episode of Care calculation

I used DOB for all the patients to identify them in my EHR. I added a new Column S (patient's first visit with me) and column T (last visit with me) in order to compare them to the episode of care. I note the following problems:

- For my most expensive patient, the START date of the episode was the LAST date that I was involved in her care. Hers is not the only such example.
- Overall, I was not involved in the care of the patients for 94% of the episode you calculated
- That means the majority of the costs were determined by another practitioner and were not under my control.
- Many patients had been in my care for weeks and yet the trigger and confirmatory codes happened at the end of their care.
- **The average true episode of care for my patients was only a few weeks. Clearly a one year episode of care is too long.**

Additionally, two of the most expensive clinicians associated with "my" patients are podiatrists. The only way that their care could be so costly was if they are using skin substitutes for which I am being held accountable. If the patient is still in "my" episode of care, do those costs NOT accrue to them since they are the ones ordering them?

In reviewing my report, I found the Directors of two other wound centers in my list of physicians. This indicates to me that the patient visited more than one Wound Center during the episode of care. This may represent the patient getting a second opinion or "doctor shopping." If this scenario results in the patient being managed by another clinician and potentially not seeking care with me any longer, I'll still be attributed the costs even though my relationship with the patient has ended (with or without my knowledge). Is that right? In this example, are there overlapping episodes? Will the Directors of the other wound centers open their own cost episodes? Will I still be attributed their costs if my relationship with the patient ends with/without my knowing?
Wound care practitioners are CONSULTANTS. We only control our own costs. We do not control the costs of other consultants, nor can we control the costs of patients who leave our practice and go elsewhere.

Where are the arterial ulcers?

I see many arterial/ischemic ulcers. That diagnosis is not listed in column C. How will you find them? How will you create a fair risk classification for them? On table 2, the arterial ulcer count is "0". Is it zero for everyone or just me? How are you finding them since they require two codes?

Many patients have multiple ulcers, but you are not classifying them that way

In looking at column C, nearly all patients with venous ulcers have multiple venous ulcers. It appears that if there are multiple ulcers of the same type, you are only able to identify them as having ONE ulcer. In your classification, "multiple" means multiple ulcer TYPES. Thus, if a patient has 10 ulcers of the same type, you do not know that and thus cannot correctly risk classify them.

I was not MIPS Eligible over this time frame but have a Field Test report

I was not MIPS eligible in the time frame of this cost measure because I was under the reporting threshold. Initially, I did not even look for a Field Test report for that reason. I was "opt in" eligible and I have submitted MIPS data by "opting in." How did that impact the cost measure calculation? **Many of my colleagues in the full-time practice of wound care do NOT have field test reports. Why would that be the case? How might it affect your evaluation of the data?**

Why are podiatry costs attributed to me when I do not refer to those podiatrists?

Two of the five "top spending" practitioners are podiatrists. I would like to understand how and if their use of CTPs (over which I had no control) contributed to my Part B costs.

It seems likely that there is a problem with the DME supply category

I order surgical dressings from DME Providers on perhaps 75% of my patients, yet I have a 0 in the category of wound care products. What then is included with "Durable Medical Equipment and Supplies" for which I am at 65.5%? I only practice two days a week. It seems likely that wound care products are actually included in the category of "Durable Medical Equipment and Supplies".

There are serious attribution problems based on Table 3

Regarding the costs attributed to "Your TIN", I assume this means the service that you have *attributed* to me regardless of whether I ordered them or whether the patient was under my care. Most of these are services that I do not order, and which are not under my control. I do not admit patients to the hospital, provide inpatient services, order speech therapy, order oxygen therapy or perform joint injections. I do not admit patients to a SNF or inpatient rehab, perform injections or infusions, or provide anesthesia services. Here is a list of the items on Table 3 that I have not ordered or performed in over 30 years:

- **Physician services for hospitalization**
- **Ultrasound**
- **Oxygen**
- **Emergency Department services**
- **Skilled Nursing facility services or admissions**
- **Physical, Occupational, or speech and language pathology therapy**
- **Inpatient rehabilitation or long term care hospital services**
- **Anesthesia services**
- **Injections and infusions**

Some things are not on Table 3 that should be:

There are a number of costs that SHOULD have been present in my report but are not. For example, I frequently refer patients for vascular services and imaging such as MRI and MRA. What about OUTPATIENT wound debridements of which I do many? Are these part of the category called "skin procedures" or does that refer to CTPs/skin subs? How are major vs. minor procedures defined? We need those detailed by CPT code.

Why aren't amputations a major focus of the report?

Why not calculate amputations for DFUs since reducing amputations related to DFUs is a major focus of CMS? Most importantly, how are all those "amputations for circulatory system disorders" calculated? What about amputations for patients who do NOT have circulatory system disorders?

Where are the reports of my colleagues who practice wound care?

Many clinicians in the full-time practice of wound care were unable to find Field Test Reports on the QPP sites, particularly those in academic and large multispecialty practice settings. Why? Was it due to ACO participation? What clinicians would not have had reports even if they had many eligible patients?

The measure suggests that Acumen does not understand wound care services

Now speaking as a member of the workgroup, I am very concerned that the Acumen team does not understand the way that wound care services are provided. For example, it does not appear that you understand what a "skin substitute" is, based on the fact that the wrong codes were included in the list of "skin grafts." We discussed this during the meeting and provided the correct codes. **Can we**

meet again to explain what these products are and how the service is provided? Why were vascular grafts included in the list? Where are charges for the skin substitutes?

How is Site of Care accounted for in the cost model?

I do not think that the Acumen team understood the importance of the of "site of service" in the cost model. In the doctors' office (site of service 11), the cost of the skin substitute product and the cost of hyperbaric oxygen therapy are allocated to the PHYSICIAN. However, when physicians provide wound care in the hospital-based outpatient department (HOPD – site of service 22), the cost of the product and the cost of the technical service are paid as part of the hospital fee and are not part of the physician payment. Additionally, all services provided in the doctor's office are paid at a higher rate than in the HOPD, in recognition of the fact that the physician is responsible for all the overhead. **This means that site of service will have a PROFOUND impact on apparent costs for wound care services.** Most wound care practitioners who are not podiatrists are working in the HOPD. **How was the cost model adjusted to account for site of service so that fair comparisons could be made?**

How did you handle the huge challenges with ulcer coding?

ICD10 codes are simply not adequate for CMS to identify the wound type. DFUs and arterial ulcers cannot be identified except by using TWO codes**. There are no "ulcer codes" that are specific to diabetic foot ulcers or arterial ulcers**. There is no standard way that these problems are identified in EHRs. Most of these problems end up being coded as non-specific ulcerations. ICD10 recommends that the underlying problem (e.g. "diabetes") is coded first. HOW DID ACUMEN HANDLE THIS? The committee tried to alert Acumen that coding guidelines would impact your ability to identify ulcers by type.

The reports are not interpretable by busy clinicians

I provide the Table below just as an overview.

Table 2: Cost Measure Performance by Episode Sub-Group

Episode Sub-Group	Your Episode Count	Share of Episodes		Mean Ratio of Winsorized Annualized Observed to Expected Cost	
		Your TIN	National Average	Your TIN	National Average
Non-Pressure Ulcers	55	100.0%	100.0%	0.87	1.11
Arterial Ulcer Type	0	0.0%	4.6%	0.00	1.16
Diabetic Ulcer Type	10	18.2%	29.1%	1.46	1.16
Venous Ulcer Type	18	32.7%	18.3%	0.51	1.10
Multiple Ulcer Types	9	16.4%	6.3%	0.63	1.09
Non-Specific Ulcer Type	18	32.7%	41.6%	1.04	1.10

Refer to the Glossary, Table A2 for definitions of metrics.

I serve on the Clinician Expert Workgroup, and yet I do not understand the tables provided in my report. What does the "Mean ratio of Winsorized annualilzed observed to expected" cost mean? Seriously, I do not know what "winsorizing" means in this context. The Cochrane Collaboration provides a "plain language" summary of even highly complex evidence analyses. Why can't CMS provide a "plain language" summary of the Field Test Reports and what they mean?

Summary of concerns

I am deeply worried about the fact that I am responsible for charges that occurred after I was no longer seeing these patients, and that the cost measure includes charges that were likely not incurred specially in the management of the wound. How can the fact that the patient is no longer under the care of the clinician be conveyed? Does the episode have to be 365 days when most wound care practitioners see patients for far less time than that? **My biggest concern is that there is no way to determine the outcome of the patient. As a result, you cannot validate your assertion that higher costs are *not* associated with better outcomes.**

As a workgroup member, I am deeply concerned that not only is there a lack of understanding of the way that services are provided, but a failure to incorporate the concerns and the input of the members. It feels as though the committee was simply a perfunctory step and that some predetermined model was followed without alteration.

Thank you for the opportunity to provide feedback on the Non-Pressure Ulcers episode-based cost measure. **The current cost measure should not be utilized.**

Yours sincerely,

Caroline E. Fife, MD