ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

November 20, 2017

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1676-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Request for Information (RFI)
Centers for Medicare & Medicaid Services: Innovation Center New Direction

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the CMS request for information (RFI) on the new direction of the Center for Medicare and Medicaid Innovation (CMMI). We request a meeting with CMS and CMMI staff to discuss many of these issues.

The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

The Alliance is a committed partner of the Health Care Payment Learning and Action Network and thus is supportive of educating our members on MACRA implementation and APM adoption.

The RFI identifies guiding principles as well as eight areas of focused model testing. The Alliance is commenting on the following:

- specialty physician models
- program integrity.
- benefit design and price transparency

We also offer additional ideas/concepts as well as recommendations for your consideration.

Physician Specialty Models

In the RFI, CMS states that the Innovation Center is interested in "increasing the availability of specialty physician models to improve quality and lower costs and engage specialty physicians in alternative payment models, especially for independent physician practices." CMS identified one potential option may be to include "specialty physician management of a defined population of beneficiaries with complex or chronic medical conditions, including multiple chronic conditions." Under this scenario, the Alliance believes that wound care patients could qualify as a defined population and serve as an example for CMMI to consider in its "physician specialty models" for the following reasons:

1. Wound care is multidisciplinary. The practice of wound care is not limited to one particular medical specialty recognized by the American Board of Medical Specialties. Instead, there are many different specialists who treat patients with chronic wounds. These practitioners include but are not limited to the following: surgeons (e.g. general surgeons, vascular surgeons, plastic surgeons, and foot and ankle surgeons), vascular medicine physicians, podiatrists, dermatologists, nurse practitioners, infectious disease experts, physical therapists, nurses, registered dietician nutritionists, and primary care physicians who are in the full time practice of managing patients with wounds.

   In addition, we encourage CMMI to think beyond a physician-focused payment model for chronic wound care and instead focus on examining the current regulatory hurdles that exist which hinder care for wound patients. One glaring example of these regulatory hurdles in wound care can be seen in the current supervision requirements that dictate which practitioners can care for wound patients. We encourage CMMI to work with Alliance stakeholders to update the supervision requirements that govern wound care so they more closely align with current certification and scope of practice requirements in the field of wound care. We believe current supervision requirements restrict patient access to quality wound care because they do not reflect the interdisciplinary approach that the field of wound medicine takes when treating patients with wounds.

2. Most wound care patients have serious complex and/or chronic co-morbid medical conditions. Non-healing wounds occur among patients with diabetes, peripheral vascular disease (nearly as common as coronary artery disease and stroke), or as a result of unique medical problems (e.g., sickle cell anemia, vasculitis), or in association with immunosuppression (e.g., AIDS, steroid use or transplantation medications). Many times the wound care costs are not taken into account since these patients may enter the hospital with a primary diagnosis of infection, cardiac disease, diabetes, kidney failure or cognitive deficits and the diabetic foot ulcer or venous stasis ulcer may not be accounted for; therefore, contributing to an underreporting of wound care expenditures. Specifically, for patients with pressure ulcers, the most common primary diagnoses for hospitalizations include septicemia, pneumonia,

urinary tract infections, congestive heart failure, respiratory failure, and complicated diabetes mellitus.[i]

3. Chronic wounds are clinically devastating and have an extraordinary impact on Medicare beneficiaries. In a comprehensive Medicare claims analysis with the most current assessment of chronic wound care expenditures for Medicare patients (based on 2014 Medicare data), data shows that chronic wounds impact nearly 15% of Medicare beneficiaries. A conservative estimate of the annual cost is $28 billion when the wound is the primary diagnosis on the claim. When the analysis included wounds as a secondary diagnosis, the cost for wounds is conservatively estimated at $31.7 billion. Surgical infections were the largest prevalence category (4.0%), followed by diabetic wound infections (3.4%). Most importantly, the study showed a shift in costs from the hospital inpatient to outpatient setting.[ii]

While wound care could possibly be the umbrella for a wound care model, each of the different wound types such as diabetic foot ulcers, venous stasis ulcers, pressure ulcers, and arterial insufficiency have their own set of protocols and care paths, and may need to be individually addressed. For example, for diabetic foot ulcers, the Society for Vascular Surgery collaborated with the American Podiatric Medical Association and the Society for Vascular Medicine to create clinical practice guidelines in 2016.[iii] Many of our clinical association members have also created additional clinical practice guidelines which we would be pleased to share with you when we meet.

We also suggest that CMMI consider that wound healing is a complicated process directly influenced by the status of medical comorbidities, he local wound environment and also by the overall physical condition of the individual. The process of wound healing involves metabolic, structural, biochemical, and patient factors in a unique way. Wound healing is not a single event; it is a result of complex overlapping processes. There are guideline-suggested interventions but there are many combinations of individual wound characteristics which contribute to the complexity of healing a wound. The order and combinations of treatments used are varied and may be directed anywhere along the wound healing cascade.

Historically, CMS has focused on care provided by specialty physicians and created the Quality Physician Payment regulations. However, if CMMI is interested in innovation, then the Alliance believes that it should be taking a more multidisciplinary approach to care and promote care coordination and create more incentives to encourage the creation of these multidisciplinary models in order to reduce costs to the Medicare program.

Wound care physicians and clinicians are a unique group of individuals—they are committed to continuously monitoring patients with chronic wounds, providing ambulatory services which decrease amputation and keep them out of the hospital. We request that the Agency advance patient care by collaborating with us on this joint journey to establish a care pathway for wound care clinicians and the patients they serve.

Benefit Design and Price Transparency

The RFI states to "use data-driven insights to ensure cost-effective care that also leads to improvements in beneficiary outcomes." The Alliance agrees evidence-based medicine as well as data driven quality improvement is key. Our focus in wound care includes the following:

- Emphasis on real world evidence in wound care rather than randomized clinical trials (RCTs)
- Importance of registry data
- Need for inclusion of wound care quality measures

Emphasis on real world evidence in wound care rather than RCTs

Currently, Medicare contractors request RCTs for coverage of products in their wound care Local Coverage Determinations (LCDs). However, RCTs are not practical in wound care delivery. Patients with chronic wounds have serious co-morbid conditions that distinguish them from the subjects of wound care RCTs. Several factors can be defined that increase the duration and cost of wound care including wound etiology, as well as specific patient factors. These patient factors likely impact the effectiveness of advanced therapeutics in ways that cannot be ascertained by RCTs.

RCTs are not able to evaluate the effectiveness of a wound care product or intervention, since more than half of patients are excluded from participation which greatly diminish the applicability of RCT results to the greater population as well as evidence-based medicine. We believe that the practice of wound care should be based on real-world evidence, which is the direction in which the FDA is currently moving, and we hope that CMS and CMMI follow.

Importance of registry data

In terms of improving health outcomes, the best way to ensure that outcomes are achieved is to collect data to determine gaps in practice and then implement performance based payment.

We believe that registry data can be utilized to ascertain this information. However, while CMS has implemented the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs), there are no performance-based measures specific to wound care. We have provided more information below on this issue; however, we have concerns that when clinicians can "cherry pick" the measures they report (and are not mandated to report on the specific services being performed) – and other care providers are involved who cannot report or may only voluntarily report – there is a disconnect between what is being done and what should be done when performance-based payment is not specifically tied to the services being performed.

Need for reporting of wound care quality measures

We strongly support the continued development of quality measures that assess wound care outcomes, as wound care clinicians should be required to report on measures that relate to the care being delivered. While the Alliance recognizes there are some quality measures specific to wound care, because wound care is not a "specialty," clinicians currently can "cherry pick" the quality measures they report. The ramifications of such selection are:

1. Those that report are providing the care to wound care patients and therefore reporting on the wound care quality measures as they use them to score positively.

2. Since reporting on wound care quality measures is not mandatory under MIPS, clinicians who will not score well on the wound care quality measures will choose to report other measures that are more favorable to their performance.

3. When all clinicians do not report measures and only those that will score well do, CMS comes to the conclusion, albeit erroneous, that there are no gaps in practice when they look at the data for those clinicians who reported.

4. CMS will eliminate measures when the agency finds these measures are "topped out." However, the only manner by which the agency can ensure that high-quality wound care is being delivered is to require that wound care measures are reported.

As such, any provider that delivers wound care services should be required to report on wound care quality measures. **If this requirement is mandatory, then additional measures will need to be created to ensure that any care in treating a patient with a wound is being represented in the quality measure set being reported.**

The documentation of the specific, significant burden of chronic wounds in the Medicare population illustrates the need for CMS and health policy makers to **include wound-relevant quality measures in all care settings as well as develop episode of care measures, chronic care models, and reimbursement models to drive better health outcomes and smarter spending in the wound care space. We are happy to discuss these issues when we meet with you.**

Program Integrity

The Alliance has consistently supported efforts to reduce fraud, waste, and abuse in the Medicare system. However, we question whether this needs to be tested in a stand-alone model. Rather, efforts to reduce fraud, waste, and abuse should be automatically included in any model design. Any initiatives by which the Medicare program can curtail fraud, waste, and abuse are generally identified by the Office of the Inspector General and the Alliance submits that the Agency should look first to those initiatives, rather than putting forth new program integrity proposals.

The Alliance maintains that errors in documentation should not be utilized to show fraud, waste, or abuse in the Medicare program. We acknowledge that errors in documentation do occur. However, when such errors are tied to reports of fraud and abuse, the true results of any fraud and/or abuse are jaded and therefore inaccurate. The Alliance recommends that no program integrity initiatives should adversely impact patient care and the ability of providers to make medically appropriate decisions regarding interventions to achieve optimal outcomes for their patients.

Other Model Concepts for Consideration

1. Patient Accountability

Patients need to have more accountability in their care. Clinicians cannot monitor whether patients are following their care plan when they are not present, yet the clinicians are held accountable. For example, if a physical therapist provides strengthening exercises for a patient to do at home but if the patient continues to come to physical therapy week after week without doing the strengthening exercises at home, it will take significantly longer for the patient's condition to improve at additional cost to the program. CMMI may want to consider a demonstration project in which patient accountability is taken into consideration. It would be helpful for the Agency to examine the mechanisms by which patients can be incentivized to follow their care plans.

2. De-Regulation Demonstration Model

There are an overwhelming number of restrictive regulations that govern the practice of health care and are not based on clinical evidence. This impacts the way the clinicians deliver care to their patients and the benefits/access to care that beneficiaries receive. The Alliance agrees with your opening remarks at the October 30, 2017 LAN Summit where you stated:

> *Regulations have their place with quality, integrity, and safety in our healthcare system. The rules that were outdated, misguided, or too complex –they can have a suffocating effect on the health care delivery system by shifting the focus of the providers away from the patient and towards unnecessary paperwork and ultimately increase the cost of care.*

We are in agreement that less regulations are needed. Therefore, we recommend that CMMI develop a model in which health care is deregulated. Care would be provided based upon best practices and what is in the best interest of the patient rather than attempting to meet arbitrary utilization parameters, choice of product, and care development in order to meet coverage policy requirements. When deregulation occurred in the airline and telecommunications industries, increased competition and consumer choice occurred. This should also be occurring in health care. For instance, there are currently examples of community care plans and other programs that are moving in this direction (e.g., North Carolina and Rhode Island) which we suggest that CMMI consider.

3. Voluntary Quality Improvement Reporting Model for Hyperbaric Oxygen Therapy (HBOT)

The Alliance partnered with the US Wound Registry (USWR) to develop 14 wound care relevant measures, many of which target proven gaps in practice. Some of them are high value measures, including risk-stratified outcome. The USWR has submitted comments to CMS on the new direction for CMMI related to Improving Integrity through Quality Improvement. The USWR suggested testing a Quality Improvement Model which would evaluate the submission of **Appropriate Use Quality Measure Data** as a mechanism to ensure compliance with Medicare coverage policy in the use of HBOT. The Alliance supports this model. Participation in this program would be optional. Clinicians achieving a defined threshold performance rate over a specific time frame would be eligible to participate. Clinicians who chose to participate in the Quality Improvement Model with CMMI would not be subject to prior authorization of HBOT, a laborious program that has thus far resulted in limited savings. Additionally, participating clinicians would not be subject to pre-payment review of HBOT, which has only added to the backlog of cases within the administrative appeals process.

This concept leverages the currently existing quality reporting program, aligning with MIPS and the Quality Payment Program. It standardizes chart reviews, avoiding the variability that exists now between the various Medicare Administrative Contractors (MACs) and individual reviewers. It also streamlines the review process and reframes and refocuses payment oversight as a quality of care initiative. Additionally, it creates immense cost savings by reducing the need for individual chart reviewers while also diminishing improper use of services. We strongly encourage the Agency to examine the benefits of such model, as this is one of many models that can be utilized in wound care, to the benefit of patients, providers, and the greater community.

4. Population Management Models

The Academy of Nutrition and Dietetics are a clinical association member of the Alliance of Wound Care Stakeholders. Since nutrition is a key component of essential wound care practice, we are in support of their comments as stated below:

> ***The Academy recommends that the model concepts include a category called population management models.*** *The Academy has reviewed the potential model concepts and is pleased to have identified some model concepts where nutrition and RDNs could fit. With the Innovation Center's emphasis on engaging beneficiaries as consumers, consumer choice, and the need to give beneficiaries the tools and information they need to make decisions that work best for them, the Academy would like to recommend a population management model category that embraces several of the aims of the proposed guiding principles. This model concept should also allow non-physician Medicare providers and inter-professional care teams to pitch models to CMS, or work with CMS to develop models, for either specific populations or conditions across multiple settings. Some examples of areas of care that might fall into this category could be wound*

care, which is not necessarily handled by a particular specialty, but includes care for multiple types of wounds, the involvement of several members of inter-professional care teams, and across multiple care settings. Population management models for nutrition could be designed for specific populations and/or conditions, involve multiple specialties and care settings, the use of validated tools, and standardized Nutrition Care Process (pathways) throughout a continuum of care.

Additional Recommendations

The Alliance requests that CMMI consider our additional recommendations:

- *Before CMMI moves forward with any new payment models in order to protect patient access to vital therapies and ensure that care is not compromised as new models are tested, we ask that it considers the following*:
    - Finalize clear safeguards within CMMI through notice and comment rulemaking.
    - Finalize safeguards that ensure that all models are small-scale, voluntary tests. Models should be tested in a limited population to minimize unintended consequences before proper testing is completed.
    - Avoid making wholesale changes to existing law, and must have a process for engaging Congress in any broader programmatic changes. Small scale, voluntary testing, with a process for engaging lawmakers prior to making permanent programmatic changes will ensure CMMI serves its core purpose as a testing ground for new payment and delivery reforms.
    - Carefully evaluate how proposed changes will impact access to care and should not incorporate elements of an existing pilot or demonstration into new payment models before proper testing is completed. Proposed models should include a strategy to monitor, assess, and quickly address changes in patient outcomes and access to care.
- *Review provider reporting and other administrative requirements related to participation in Medicare.* While we are supportive of the movement to value-based care, the burden being placed on providers with regard to Medicare participation, including quality and other metric measurement and reporting, should not be overlooked or minimized. We urge CMMI and CMS to assess the impact of measurement and reporting requirements on providers, including whether it takes away from patient care, and how to make them more efficient and effective. CMMI could also create Requests for Proposals (RFPs) on research from quality metric organizations, such as the US Wound Registry, to determine which metrics are most consequential to improving outcomes in order to create a set of core evidence-based wound care measure set that significantly impact value. In addition, CMMI and CMS should address technology requirements that limit providers' ability to provide comprehensive patient care, such as barriers for all to electronic health records (EHRs).
- *Ensure that APMs are multidisciplinary.* The Alliance recommends that CMS mandate the inclusion of functional measures within APMs that show the value of providers who have traditionally been excluded from APM participation. Any new

model should include appropriate measures that address function and capture the value of each provider involved in patient care in the APM population.

- *CMS needs to more efficiently encourage coordination and communication between health care professionals in order to improve patient outcomes and quality of care.* In doing so however, it should not create an increased financial or administrative burden on health care providers.
- *HCPCS coding reform* As CMMI looks to alternative payment models, it should be aware that payment and coding are related. Therefore, CMMI should request that CMS reform the current Healthcare Common Procedure Coding System (HCPCS) coding process for Level II alpha-numeric codes.

  It is used by Medicare, Medicaid, and private health plans and the process is not transparent, understandable or predictable. Over the years, this has created strong barriers to appropriate coverage and reimbursement for new technologies and products. The current process has a chilling effect on innovation that drives researchers and R&D investments away from durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) ultimately compromising access to quality care for millions of Medicare beneficiaries and other individuals. Although this process is administered by the Centers for Medicare and Medicaid Services, this badly flawed process impacts Medicare and all payers using the uniform code set. Reform is needed to ensure the goals of a meaningful code set are met, namely, uniformity in billing, appropriate coverage and reimbursement policies, and patient access to quality care.

  The Alliance recommends that since CMMI is addressing payment models which currently correlate with coding, that the following be done:

  - Increase transparency of coding decisions and adopt procedural protections to enable stakeholders to participate in the coding decision process, including a mechanism for stakeholders to respond to coding decisions. We further recommend the creation of a HCPCS Level II Coding Advisory Committee to assist the HCPCS Coding Workgroup;
  - Clearly separate the criteria used to establish a new HCPCS code (or verify use of an existing code) from criteria used to establish a coverage policy for the product(s) described by that code. Coverage criteria should never be considered when making coding decisions;
  - Establish a transparent appeals process to provide an independent review or reconsideration of coding decisions; and
  - Improve the coding verification process used by the Medicare Pricing, Data Analysis and Coding contractor (the "PDAC"), as well as the CMS-initiated code revision process (e.g., for internal or modifying code descriptor).

- *Claims data is often used to set cost targets and model design.* However, claims data is vastly insufficient to glean a complete understanding of the contribution and/or cost-effectiveness of numerous health care services and providers. Model design and evaluation should strive to incorporate care provided by cost effective providers

emphasized in evidence-based guidelines.

Conclusion

The Alliance appreciates the opportunity to provide our feedback to CMS on the new direction of CMMI. We look forward working with you. **The Alliance would be happy to meet with CMS and CMMI to further discuss these options as well as serve as a resource for you.** If you have any questions or would like further information please do not hesitate to contact us.

Sincerely,

Marcia Nusgart, R.Ph
Executive Director

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[i] Sen Chandan K. et al "Human skin wounds: A major and snowballing threat to public health and the economy." Wound Rep Reg. 2009 17 p. 764.

[ii] ***An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds*** Nussbaum, Samuel R. et al., Value in Health, in press http://www.valueinhealthjournal.com/article/S1098-3015(17)30329-7/pdf.

[iii] Hingorani, Anil et al, The management of the diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine, Journal of Vascular Surgery, February Supplement 2016, 3S-21S