

Wound Care Manufacturers

June 16, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation [CMS-1771-P]

Dear Administrator Brooks-LaSure:

On behalf of the Coalition of Wound Care Manufacturers (“Coalition”), I am pleased to submit comments on the Hospital Inpatient Prospective Payment Systems for Acute Care and Long Term Care Hospitals for federal fiscal year FFY 2023 . The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds – including those with pressure ulcers/injuries.

While there are many provisions proposed in this regulation, the Coalition is focused on these areas:

1. Hospital Harm – Pressure Injury electronic clinical quality measure (eCQM)
2. The PSI-90 Composite Measure
3. CMS Adoption of Global Malnutrition Composite Score NQF #3592

Our specific comments follow.

Hospital Harm – Pressure Injury Electronic Clinical Quality Measure (eCOM)

On February 24, 2020, the Coalition submitted a request to CMS that as the Agency

developed regulations for the Inpatient Prospective Payment System, that the Hospital Harm – Pressure Injury electronic clinical quality measure (eCQM) be included. While this measure was included in the proposed CY 2020 rulemaking, it was not included in the final CY 2020, Inpatient PPS rule nor was it included in the recent CY 2023 proposed rule. We understand that CMS is continuing to perform validation of this measure, and hope that CMS proposes to include this measure in the CY 2024 proposed rule especially since the burden of illness for pressure injuries is well documented by CMS as noted in its May 2019 IPPS proposed rule.

Wound care is a national epidemic masked by comorbidities. Nearly 60 million people in the U.S. are living with diabetes or vascular disease, which are the leading causes of chronic wounds. Over 6.7 million patients suffer from non-healing advanced wounds, leading to unnecessary hospitalization and lower extremity amputations. Patients with chronic wounds have longer lengths of stay, unplanned readmissions, and costs to treat. In fact, a recent study shows that *chronic wounds impact nearly 20% of Medicare beneficiaries (over 11 million) and cause as much as \$35 billion in Medicare expenditures (including both fee-for-service and Medicare Advantage)*. (Nussbaum, Carter, Fife et al. "An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds" *Value in Health* 2017).

Additionally, pressure injuries are considered a common patient “hospital harm” and can lead to serious health events for patients. An estimated 1.19 million hospital-acquired pressure injuries occurred in the year 2015. Pressure injuries commonly can lead to local infection, osteomyelitis, anemia, and sepsis; in addition to causing significant depression, pain, and discomfort to patients. The presence or development of a pressure injury can increase the length of a patient’s hospital stay by an average of four days, which can increase the spending ranging from \$20,900 to \$151,700 per pressure injury.”

The Hospital Harm - Pressure Injury eCQM would reduce pressure injury prevalence through rate transparency utilizing complete data extraction of Electronic Health Records (EHR). This would encourage hospitals to adopt best practices identified by international pressure injury prevention bodies, including the National Pressure Injury Advisory Panel (NPIAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) and 15 associate organizations from multiple countries. These guidelines are brand agnostic, evidence-based, and call for the following practices to drive pressure injury prevention.

The adoption of a Pressure Injury eCQM would dramatically reduce pressure injury incidence and improve the quality of care for Medicare beneficiaries. Moreover, it would provide hospitals with reliable and timely measurement of their pressure injury rates, and create valuable public transparency for hospitals and patients on the prevalence of these debilitating events.

We know that hospitals can make meaningful strides to reduce the incidence of these harmful conditions by gaining timely and accurate data on the prevalence of pressure injuries at their facilities. Adoption of evidence-based protocols will drive improvement in care quality.

To that end, the Coalition urges CMS to validate and propose the pressure injury eCQM as soon as possible to allow better tracking of pressure injury care in hospitals, ideally through the FY 2024 hospital inpatient proposed rule.

PSI-90 Composite Measure

CMS has proposed to suppress the PSI-90 Composite Measure. While the Coalition understands that hospitals experienced significant burdens as a result of the COVID 19 Public Health Emergency (PHE), the Coalition recommends that CMS reinstate PSI-90 as soon as possible as hospital burdens resulting from the PHE are currently much less and hospitals are likely getting back to normal and implementing for example pressure injury reduction protocols. Should CMS continue to suppress or eliminate the PSI-90 measure, the Coalition recommends that the Agency replace the PSI-90 with PSI-03, and treat this as a stand-alone measure. Implementing pressure injury reduction protocols will significantly help hospitals reduce the number of Hospital Acquired Conditions (HAC).

AHRQ released a National Scorecard on Hospital-Acquired Conditions (Updated Baseline Rates and Preliminary Results 2014-2016). The scorecard shows that the rate of overall hospital acquired conditions (HACs) has decreased 17%, saving \$19.9 billion in health care costs and preventing 87,000 deaths. Yet, it is also noted **that data for pressure ulcers/injuries from the same period of time showed an increase of 10%**. Considering the burden of pressure ulcers/injuries for patients in hospitals (preliminary 2016 $\geq 700K$) and the additional cost per patient of over \$14.5K, the Coalition believes it is important to keep the PSI-03 pressure ulcer measure active. This will not only benefit the Agency but also patients and hospitals as well.

Pressure ulcers/injuries are complex and due to the incidence and the interest of the community, the development of evidence-based protocols should be used and not minimized in a composite measure with other factors – such as those contained in the PSI-90. The scorecard highlights the CMS goal to reduce hospital acquired conditions by 20% from 2014 - 2019 – including pressure ulcers/injuries – and recognizes that there are opportunities for further improvement in reducing harm. Eliminating measures which focus on pressure ulcers/injuries is not in the best interest of the patient. Given the attention that pressure ulcers/injuries receive in regulations (hospital acquired conditions and adverse events) and the recent score card highlighting their increase, the Coalition recommends that CMS reinstate the PSI-90 measure OR if the Agency decides to continue its suppression, that CMS replace the PSI-90 with PSI-03, and treat it as a stand-alone measure. Use of PSI-03 as a stand-alone measure will maintain focus on pressure

ulcers/injuries. It would lead to better reporting since the measure will solely focus on pressure ulcer safety and adverse events which will lead to improved patient care.

Adoption of the Global Malnutrition Composite Score, NQF #3592

The Coalition is a member of the Alliance of Wound Care Stakeholders who have been on record supporting the adoption of the Global Malnutrition Composite Score NQF #3592 and will be submitting comments advocating for CMS to finalize this measure. The availability of malnutrition quality measures in both inpatient and long-term care programs will help providers connect the dots and ensure effective transitions of care are in place for critically ill malnourished patients requiring long-term care. Malnutrition negatively impacts hospital readmissions, length of stay, wound healing and morbidity and mortality. There is a reference that provides a summary of literature linking malnutrition to hospital-acquired conditions (HAC), readmissions, length of stay, and pressure injuries¹. Malnutrition leads to a reduced quality of life for our nation's seniors as well as increased costs of care.²

The Global Nutrition Composite Score is a publicly supported measure that focuses on malnutrition quality of care and we applaud the Agency for its inclusion in this proposal and the Coalition recommends its adoption.

Conclusion

In summary the Coalition recommends that:

1. CMS include the Hospital Harm - Pressure Injury eCQM in the CY 2023 Inpatient PPS final rule, or alternatively, propose this eCQM in next year's CY 2024 IPPS rule.
2. CMS should either reinstate the PSI-90 composite measure or create a stand-alone quality measure for PSI-03, Pressure Ulcer Rates.
3. CMS adopt and include in its final rule NQF #3992 the Global Malnutrition Composite Score.

The Coalition appreciates the opportunity to provide our written comments. Should you

¹ Phillips W, Doley J. Granting order writing privileges to registered dietitian nutritionists can decrease costs in acute care hospitals. JAND. 2016; DOI: <http://dx.doi.org/10.1016/j.jand.2016.06.009>.

² Kaiser MJ, et al. J Am Geriatr Soc. 2010;58(9):1734-1738. 2. Snider JT, et al. JPEN J Parenter Enteral Nutr. 2014;38(2 suppl):77S-85S. 3. Barrett ML, Bailey MK, Owens PL. U.S. Agency

have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink that reads "Karen Ravitz". The signature is written in a cursive style with a light blue background behind the text.

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