

Wound Care Manufacturers

June 22, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1750-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1750-P - 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 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment

Submitted Electronically to www.regulations.gov

Dear Ms. 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. 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 those that impact wound care. As such, our comments focus on these areas:

1. Hospital Harm – Pressure Injury electronic clinical quality measure (eCQM)
2. New Technology add-on payment extensions
3. The PSI-90 Composite Measure
4. 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 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 or 2021 Inpatient PPS rule nor was it included in the recent CY 2022 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 2023 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).

We understand that CMS continues to consider a Hospital Harm – Pressure Injury electronic clinical quality measure (eCQM) for future rule making. The Coalition supports and encourages 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 that they deliver allowing CMS to effectively track and report the quality of that care. As such, the Coalition strongly supports this measure, as it would encourage hospitals to adopt evidence-based protocols, practices and technologies that reduce the risk of pressure injuries and improving care for Medicare beneficiaries. Furthermore, this measure is designed to reduce pressure injury prevalence through rate transparency utilizing complete data extraction of Electronic Health Records (EHR). We believe that pressure injury rate transparency will lead hospitals to identify and implement best practice improvements, which will reduce hospital-acquired pressure injuries.

With the expectation that hospital validation of the EMR based quality measure for pressure injuries will be successful, we urge CMS to propose to include the Hospital Harm - Pressure Injury eCQM in the CY 2022 Inpatient PPS final rule, or alternatively, propose this eCQM in next year's FY 2023 IPPS rule.

New Technology Add-On Payment Extension

The Coalition is also providing feedback on a provision that is included in the CY 2022 proposed rule: the potential extension of new technology add on payments (NTAP) due to the public health emergency (PHE). We agree with CMS that one year extension for NTAP items that were limited in use because of the PHE should be granted an extension. However, this consideration should only apply for drugs/devices that had the original 2-3 years of their NTAP status be issued during the PHE and thus cut short. **CMS should not extend NTAP status to any drugs/devices that had 3 years or more prior to the PHE.** While we appreciate that products that currently maintain NTAP status with less than three years of that status may not be fully benefitting during the PHE due to reduced surgical procedures, we strongly believe that items that have had more than three years of status *prior* to the start of the public health

emergency have maximized the full benefit of that status, have generated significant data for the Centers for Medicare and Medicaid Services, and are not in need of further NTAP status time.

As such, the Coalition recommends that if CMS moves forward with granting NTAP extensions to any item - that the extension should ONLY be granted to those drugs or devices in which the 2-3 year NTAP status took place within the timeframe of the PHE. Any product with NTAP status already lasting 2-3 years prior to the start of the PHE should not receive this extension.

PSI-90 Composite Measure

In this proposed rule, CMS has proposed to drop the PSI-90 composite measure. While the rationale for doing so makes sense in general, it does not for Pressure Ulcer/Injuries and specifically the PSI-03 measure.

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) 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 = >700K) and the additional cost per patient of over \$14.5K, the Coalition believes it is important to keep PSI-03 pressure ulcers 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. 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 retain the PSI-90 measure OR if the Agency decides to eliminate the PSI-90 measure, that CMS replace the PSI-90 with PSI-03, and treat this measure as a stand-alone measure. Use of PSI-03 as a standalone 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 add this measure. This is a publicly supported measure that focuses on malnutrition quality of care. The measure received support for inclusion by the Measures Application Partnership (MAP) pending NQF endorsement which was recommended recently by the respective endorsement committee.

We commend CMS for expressing their interest in malnutrition measures in the long-term acute care setting as this is an important step forward. To be successful, long-term care providers would benefit substantially from receiving standardized nutrition care data for malnourished patients. These nutrition care data are generated from providers in the hospital prior to transfer to a long-term care facility. Moreover, they are the same data measured in the hospital-based malnutrition composite 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.

We urge CMS to include this measure in its final rule.

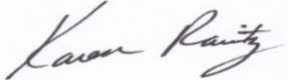
Conclusion

The Coalition appreciates the opportunity to provide you with our comments. In summary we recommend that:

1. CMS include the Hospital Harm - Pressure Injury eCQM in the CY 2022 Inpatient PPS final rule, or alternatively, propose this eCQM in next year's FY 2023 IPPS rule.
2. CMS should not extend NTAP status to any drugs/devices that had 3 years or more prior to the PHE.
3. CMS should either maintain the PSI-90 composite measure or create a stand-alone quality measure for PSI 03, Pressure Ulcer Rates.
4. CMS adopt and include in its final rule NQF #3992 the Global Malnutrition Composite Score.

If the Agency needs further information or has any questions, please do not hesitate to contact me.

Sincerely,



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