ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
Attention:CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to **http://www.regulations.gov**

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit comments in response to the proposed CY 2020 Physician Fee Schedule. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based 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 who not only possess expert knowledge in treating complex chronic wounds, but also in wound care research. A list of our members can be found on our website: http://www.woundcarestakeholders.org/about/members. Our specific comments follow.

Evaluation and Management Codes

In the hopes of easing documentation requirements, CMS proposed in the CY 2019 physician fee schedule to consolidate payment for certain office / outpatient Evaluation and Management (E/M) services and this would have led to significant reductions in reimbursement for certain providers. In our comments, we were opposed to the collapsed payment rate for office and outpatient E/M visits for level 2 – 4 and were disappointed that CMS did not change this in the 2019 Final Rule. Thus, in this CY 2020 proposed rule, we are pleased to now support the CMS decision to rescind this policy and restore separate payment for level 2-5 new patient and level 1-5 established patient office / outpatient E/M services, and to accept the RUC recommendations for the revaluing of these codes.

However, along with accepting the RUC recommendations for the values of these codes, the Agency must also apply these updated values to the global procedure codes. **The Alliance is adamantly opposed to CMS not accepting the RUC recommendation to extend the value changes in office and outpatient E/M visits to global codes and urges CMS to adopt the RUC's recommendation of commensurately**

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including the updated E/M values in procedure codes with global periods. Implementing new values for E/M codes when billed independently but not implementing those same values in the global packages disrupts the relativity in the entire physician fee schedule. Maintaining relativity across codes in the fee schedule is inherent to the resource-based relative value unit (RVU) system. In all previous revaluations of the E/M codes, post-operative visits in the global periods were updated to reflect the new values including in 1997 (the first Five-Year Review), in 2007 (the third Five-Year Review), and in 2011 (when the elimination of consultation codes created budget neutrality adjustments affecting office visits).

The RUC represents the entire medical profession – including most of our Alliance medical specialty society and clinical association members. They voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. **The Alliance agrees with the RUC and urges CMS to adopt the its recommendation.**

RAND Reports

As part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress mandated that CMS collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. The Act specified that CMS should use this data and other available data, as appropriate, to improve the valuation of surgical global services. CMS contracted with the RAND Corporation to comply with the data collection requirements. Three new RAND reports were utilized by the Agency in this proposed rule resulting in CMS proposing to pay surgeons at a different rate from other physicians and distort the relativity within the established RBRVS. The Alliance has significant concerns with the RAND reports, including the following:

- The RAND analysis utilized incomplete claims data
- The RUC has indicated that the RAND reports are already outdated.
- The data utilized in the reports as well as the resulting analysis is significantly flawed

The Alliance urges the Agency to follow the RUC recommendation that "CMS instead indicate specific codes for which they believe are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period." Furthermore, APMA, an Alliance member, has submitted very detailed comments to the Agency. The Alliance agrees with the comments developed by APMA and urges CMS to adopt their recommendations. Finally, the RUC voted 27-1 to submit recommendations to CMS to apply the RUC office visit recommendations to both the stand-alone E/M office visit codes and the E/M office visit component of the codes with global periods (010, 090, and MMM). The Alliance urges CMS to finalize a policy that adopts this RUC recommendation.

CMS has also requested specific comments on the three RAND reports. The specific Alliance comments follow:

RAND Report 1: Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods

As stated, the Alliance believes that there are several flaws in the reports. The flaws in this report include, but are not limited to the following:

- 54% of physicians eligible for this project were not aware that they were required to participate or they were unable to participate. Thus, the dataset utilized by RAND cannot reasonably be used to forecast any overall trends, given the limited and likely intermittent participation of eligible physicians as well as the current difficulty CMS and RAND researchers have implied in matching up procedures to CPT code 99024.
- RAND concluded that only 39 percent of 090-day global visits and 4 percent of 010-day global visits were performed**.** However, as stated above, 54 percent of physicians in the nine states who were eligible to participate, did not do so. Additionally, RAND inappropriately assumes that each of these physicians did not provide any office visits in any surgery's global period.
- Participation also varied widely by both specialty and state which will impact the data collection and thus the analysis and conclusions reached.
- The study used physician time files that are several years old thus making the reports outdated.
- RAND definition to categorize study participants as robust reporters as , "ten or more 90-day global procedures performed and half of those procedures include at least one reported visit reported during the global period…" which excludes any providers that only perform 010-day global procedures.
- The top three 010-day global codes, CPT 17000, 17004 and 17110, make up 65 percent of the utilization for all 010-day global services in the study. These three codes are typically performed by the same specialty, Dermatology, and are all from the same destruction of benign or premalignant lesions code family.

RAND Report 2: Survey-Based Reporting of Post-Operative Visits for Select Procedures with 10- or 90-Day Global Periods

The flaws in this report include, but are not limited to the following:

- RAND's main conclusion in the second report was that the average visits were somewhat longer for complex wound repair [21.8 minutes vs 16 minutes] and lower for other areas. However, RAND may have misinterpreted the findings of their survey data. It appears that RAND only compared the survey physician time "on the day of the visit" to the CMS physician time file, but the pre-service and post-service time of E/M services is not specific to the date of the encounter. This is an example of why CMS should be utilizing the RUC recommendations
- RAND also inappropriately excluded nurse practitioner (NP) and physician assistant (PA) time from their visit time comparison analysis and the wound repair time analyses., which would have led to the observed times being much more similar to the average CMS time cited in the comparison analyses.
- RAND categorized NP/PA survey data as "staff time" and incorrectly observed that "…*such staff time would be considered as part of PE in the RUC process and not contribute to the physician time component nor to the level of the visit."*
- The researchers did not account for Medicare rules on "incident to" and split/shared E/M services.
- Comparing day of service time to the CMS time file was not accurate.
- Survey respondents were provided with completed examples of the surveys. While acknowledging "… that providing sample surveys could potentially affect survey responses…", RAND still included this tool to help the survey respondents understand the survey burden.

Rand Report 3: Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods

The flaws in this report include but are not limited to the following:

- This study utilized the flawed reverse building block methodology to estimate the change in Medicare payment relative to the first study. The RUC has stated that reverse building block methodology, or any other purely formulaic approach, should never be used as the primary methodology to value services. The Alliance supports and agrees with the RUC's assessment.
- The "robust reporters" concept highlighted in the first study was disregarded and there was no attempt to filter out the 54 percent of eligible providers that did not participate in the data collection initiative.
- No specialty achieved a 100 percent participation rate, and therefore all codes included in the study would have been undercounted.
- Applying an overall ratio from a pool of data where all non-participants were categorized as physicians that never perform post-operative services is not appropriate and skews the analysis.
- The researchers "computed the total post-operative visit time by subtracting pre- and intra-service time from the total physician time." However, this method would have included immediate post-service time, which does not coincide with any bundled visits, as part of the bundled post-operative visit time.

Implementation of the methodology outlined in the RAND reports would result in unreasonable reductions in total Medicare payment for many surgical specialties, putting at risk access to care for Medicare beneficiaries.

As stated above, the Alliance **recommends that CMS follow the RUC recommendation that "CMS instead indicate specific codes for which they believe are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period**

RVUs for Physical Therapy

Treating patients with chonic wounds is usually performed with a multidiscliplinary team. Physical therapists are one of many disciplines of practitioners who treat patients with wounds. There is concern that many providers that do not bill for office visits using the E/M codes, including physical therapists, will experience significant decreases in both the work and practice expense (PE) relative value units (RVUs). This decrease will cause a serious financial strain on outpatient physical therapy providers.

The Alliance requests that CMS **reimburse physical therapists at a level that will continue to allow them to deliver high-quality care to their patients**. The significant reduction in reimbursement for physical therapy services will result in a decreased workforce and an inability to meet the needs of the Medicare population. If CMS intends to move forward with significant payment reductions for physical therapists, then we urge CMS to work with Congress to add physical therapists to the list of providers that may opt out; otherwise, beneficiary access to physical therapy will be severely limited.

We also urge CMS to seriously consider and adopt the recommendations submitted by APTA, one of our the

Alliance members. APTA has submitted extensive comments on this issue. **We recommend that CMS work with APTA to ensure that physical therapists are not adverstly impacted by the Agency's proposal**.

PE RVUs for Disposable Negative Pressure Wound Therapy (CPT Codes 97607 & 97608)

The Alliance would like to applaud CMS in proposing to assign an active status to CPT codes 97607 and 97608 and accepting the RUC – recommended work RVU of 0.41 for CPT code 97607 and work RVU of 0.46 for CPT code 97608, thus establishing a national fee schedule amount for CY 2020 in the physician office setting. The Alliance has been a proponent of establishing a national fee schedule for disposable negative pressure wound therapy over the years and supports this proposal.

However, CMS stated that a search of publicly available commercial pricing data suggest that a unit price of $100 may be appropriate, and therefore, CMS has proposed using this supply price in its calculation of the office-based practice expense payment.

The Alliance has strong concerns regarding this $100 supply price, as it does not approach the actual costs incurred by physicians when providing single-use disposable NPWT devices to their wound care patients in the office.

In order to ensure rate setting accuracy, we urge CMS to rely upon objective third party data sources on device costs or actual invoices showing prices paid by physicians for dNPWT devices when providing office-based care.

The Alliance recommends that CMS finalize this proposal to establish a national rate for these CPT codes, but it is critical that that a more realistic and verifiable device price be used by CMS to ensure the direct cost inputs for these services reflect actual physician costs.

Open Wound Debridement (CPT Codes 97597 and 97598)

The language in the proposed rule states:

"CPT code 97598 (Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof) was identified by the RUC on a list of services that were originally surveyed by one specialty but are now typically performed by a different specialty. It was reviewed along with CPT code 97597 (Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less) at the October 2018 RUC meeting.

CMS disagrees with the RUC-recommended work RVU of 0.88 for CPT code 97597 and has proposed a work RVU of 0.77 based on a crosswalk to CPT code 27369 (Injection procedure for contrast knee

arthrography or contrast enhanced CT/MRI knee arthrography).

CMS is proposing the RUC-recommended work RVU of 0.50 for CPT code 97598. CMS also is proposing the RUC-recommended direct PE inputs for all codes in the family."

The Alliance supports CMS's decision to incorporate the RUC Work RVU recommendation and proposal to adjust the work RVU in CY2020. However, the Alliance does not agree with CMS's proposal to provide a different RVU amount. We question why did CMS decide to not use the AMA RUC Work RVU amount? CMS disagreed with the RUC recommended work RVU and has proposed to decrease the work RVU from 0.88 to 0.77. While the Agency states that they disagreed with RUC recommended work RVU of .88 for CPT code 97597 and is proposing a work RVU of .77, the basis for this decision is on a crosswalk to CPT code 27369 Injection procedure for contrast knee arthrography or contract enhanced CT/MRI knee arthrography. We believe that there is no connection with these 2 services.

The RUC recommended work RVU is based on robust survey data. The RUC thoroughly analyzed this code by review of history, survey data and magnitude estimation to other similar services. CMS should use valid survey data in establishing the work RVUs for services.

Therefore, CMS should be commended for increasing the 97597 work RVU but **the Alliance does not agree with CMS not adopting the RUC recommendations and would urge the Agency to accept the work RVU of .88 for CPT code 97597.**

Ultrasonic Wound Assessment (CPT Code 97610)

Language in the proposed rule states:

"In 2005, the AMA RUC began the process of flagging services that represent new technology or new services as they were presented to the Committee. CPT code 97610 (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) was flagged for CPT 2015 and reviewed at the October 2018 RAW meeting. The Workgroup indicated that the utilization is continuing to increase for this service, and recommended that it be resurveyed for physician work and practice expense for the January 2019 RUC meeting.

CMS is proposing the RUC-recommend work 0.40 for CPT code 97610. CMS also is proposing the RUC-recommended direct PE inputs for CPT code 97610"

The Alliance agrees and supports the proposals in which CMS adopted the RUC recommended work and PE inputs for CPT code 97610 and recommends that CMS finalize this proposal in the final rule.

Topped out Measures

CMS has proposed to remove multiple measures from the MIPS in 2020 due to topped out status. While we are not commenting on the specific measures being removed, the Alliance is concerned about the process of removing measures for being "topped out". It is our understanding the the US Wound Registry is submitting comments about the proposed MIPS Value Pathways, a topic the Alliance looks forward to addressing in person with CMS.

In the past, the Alliance had grave concerns that CMS eliminated certain wound care measures from the US Wound Registry – a QCDR - because the Agency erroneously believed that high performance rates meant no gap in practice existed. Yet, CMS created a system in which high quality scores are linked to possible monetary rewards and therefore, by design, practitioners report the measures for which they score the highest. As long as clinicians can report any quality measures they wish, it is not possible for the QCDR to mandate any particular suite of measures. As such, wound care practitioners can choose to report on measures specifically identified in the Quality Payment Program (QPP), which have nothing to do with their practice. Clinicians *who have a gap* in practice will not report on measures that show any gap in practice – especially when there are other measures that they can report. Clinicians who *do not have a gap in practice will report on those measures and* score well (otherwise they would not report it).

Furthermore, these are measures that CMS has evaluated, vetted, and accepted. Therefore, the process to confirm that these are worthwhile has already taken place. Performance of these measures at a high rate should therefore be encouraged. Providers who are performing these quality measures should be incentivized to continue to do so. **Removing measures or declaring them topped-out accomplishes the exact opposite, which is to disincentivize the performance of a measure that CMS already deemed to be a demonstration of quality care. Many of these measures are performed in order to comply with the QPP**. It is naïve to assume that providers will continue to perform these actions at a high rate if CMS removes these measures.

Thus, the Alliance has significant issues with how CMS rejects measures when the measure tops out. The system CMS has created is designed to produce measures with only high scores since practitioners can cherry pick the measures they report and thus will report the measures in which they score well. As such, the **Alliance recommends that CMS develop a more comprehensive approach to determining which measures should be topped out**. Currently, practitioners choose which measures they report and how they report them. This voluntary reporting leads to cherry picking - reporting only measures on which they perform best or only on a sample of the relevant population. An accurate picture of topped out measures requires more universal data collection with mandatory reporting on a clinicians entire population – even for practitioners who are not part of a specialty – such as wound care practitioners.

As such, the Alliance **urges CMS to conduct a more thorough analyses of factors potentially influencing topped out performance**. For example, CMS should consider factors such as whether performance varies by group versus individual reporting, by practice setting, by geography, by volume of cases, or by physician experience with quality reporting.

CMS states that it will take other factors into consideration when considering the removal of a topped out measure, such as whether the removal would impact the number of measures available to a specialist or if the measure addresses an area of importance to the Agency. However, there is little discussion in this rule about whether and how these other factors were considered for each measure proposed for removal. Therefore, the **Alliance recommends that CMS be more transparent when developing a process for measure removal and not remove any of these important quality measures in the meantime.**

Transparency

The Alliance contines to urge the Agency to be more transparent in the development of policies. There are a significant number of cuts being proposed in this CY 2020 rule. The information provided in the rule is very

limited and does not provide sufficient information regarding the data and analysis used to determine the cuts being provided. Considering the magnitude of the cuts proposed in this rule for 2020, it is critical that CMS ensure that the process it uses to develop policies is transparent and decisions are based on accurate information.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart, R.Ph.
Executive Director