CMS issued a wide range of proposed rules within a very short timeframe. A summary of provisions within the proposed rules which the Alliance of Wound Care Stakeholders might be interested have been provided below. The proposed rules are provided in order of when the comments are due – and not necessarily in order of importance to Alliance members.

Here is a list of the proposed rules and the deadlines to submit comments. The summaries following below.

- Patient relationship categories- comments due- **August 13, 2016**
- End-Stage Renal Disease Prospective Payment System./DME Comments Due **August 23, 2016**
- CY 2017 Home Health PPS Rate Update: Home Health Value-Based Purchasing Model and Home Health Quality Reporting Requirements- Comments due – **August 26 2016**
- Appeals: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures. Comments due **August 29, 2016**
- Medicare Physician Fee Schedule: Comments Due **September 6, 2016**
- Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Comments due: **September 6, 2016**

Information of Action Plan for Further Improvement of Nursing Home Quality as FYI

A/B MAC draft LCD and comments due:
- CGS Cellular and/or Tissue Based Products for Skin Wounds- Comments Due **August 8, 2016**
- Noridian draft LCD policy regarding Hyperbaric Oxygen Therapy. Comments Due **August 8, 2016**

**Patient Relationship Categories**

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) required that CMS establish classification code sets for physician-patient relationships. The patient relationship categories and codes are intended to help CMS more effectively measure resource use, a major performance category under the Merit-based Incentive Payment System (MIPS). The patient relationship categories and codes also could be utilized through alternative payment models (APMs).

The proposed categories, excerpted from the CMS announcement regarding the patient relationship categories, include:
Continuing Care Relationships: The clinician who is the primary health care provider responsible for providing or coordinating the ongoing care of the patient for chronic and acute care. Examples include but are not limited to: Primary care physician providing annual physical examination (outpatient); geriatrician caring for resident (Nursing Home); nurse practitioner - providing checkups to adult asthma patient (outpatient).

This can also be the clinician who provides continuing specialized chronic care to the patient. Examples include but are not limited to: Endocrinologist (inpatient or outpatient) treating a diabetes patient; cardiologist for arrhythmia; oncologist (inpatient or outpatient) furnishing chemotherapy or radiation oncology.

Acute Care Relationships: Clinician who takes responsibility for providing or coordinating the overall health care of the patient during an acute episode. Examples include but are not limited to: Hospitalist caring for a stroke patient (inpatient); gastroenterologist performing a colonoscopy (outpatient ambulatory surgery); Orthopedist performing a hip replacement; urgent care practitioner caring for a patient with the flu (ambulatory); emergency room physician assistant treating a motor vehicle accident patient (outpatient), attending at a Long Term Care Hospital or Inpatient Rehabilitation Facility.

Additionally, clinicians who are a consultant during the acute episode. Examples include but are not limited to: Infectious disease specialist treating a patient for sepsis or shingles; gastroenterologist performing an upper endoscopy on a hospitalized patient (inpatient); rheumatologist performing an evaluation of an acutely swollen joint upon referral by a primary care physician; dietician providing nutritional support to an Intensive Care Unit patient (inpatient).

Acute Care or Continuing Care Relationship: This includes clinicians who furnish care to the patient only as ordered by another clinician. Examples: Non-patient facing Clinicians such as pathologists, radiologist, and other practitioners who care for patient in specific situations ordered by a clinician but have very little or no relationship with a patient.

In the announcement, CMS solicits comment on these relationship categories and a series of other issues related to their development - like how to capture relationships of doctors in Skilled Nursing Facility or Long Term Care settings.

CMS is seeking comments on the categories as well as additional relationships or modification to these relationships. Specifically, CMS has posed the following questions:

1. Are the draft categories clear enough to enable physicians and practitioners to consistently and reliably self-identify an appropriate patient relationship category for a given clinical situation? As clinicians furnishing care to Medicare beneficiaries practice in a wide variety of care settings, do the draft categories capture the majority of patient relationships for clinicians? If not, what is missing?

2. As described above, we believe that there may be some overlap between several of the categories. To distinguish the categories, we are considering the inclusion of a patient relationship category that is specific to non-patient facing clinicians. Is this a useful and helpful distinction, or is this category sufficiently covered by the other existing categories?

3. Is the description of an acute episode accurately described? If not, are there alternatives we should consider?
4. Is distinguishing relationships by acute care and continuing care the appropriate way to classify relationships? Are these the only two categories of care or would it be appropriate to have a category between acute and continuing care?

5. Are we adequately capturing Post-Acute Care clinicians, such as practitioners in a Skilled Nursing Facility or Long Term Care Hospital?

6. What type of technical assistance and education would be helpful to clinicians in applying these codes to their claims?

7. The clinicians are responsible for identifying their relationship to the patient. In the case where the clinician does not select the procedure and diagnosis code, who will select the patient relationship code? Are there particular clinician workflow issues involved?

8. CMS understands that there are often situations when multiple clinicians bill for services on a single claim. What should CMS consider to help clinicians accurately report patient relationships for each individual clinician on that claim?

Comments are due to CMS on August 13, 2016

ESRD DME Proposed Rule

On June 24th, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule to revise payment rates and policies related to the competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). Currently NPWT is one of the wound care products that would be subject to the provisions of this proposed rule. CMS proposes the following changes to the DMEPOS competitive bidding program:

- Revise the limits on bids for individual items for future competitions so that they are based on the otherwise applicable unadjusted fee schedule amounts.
- Establish an alternative to the current bidding methodology for product categories that include two or more similar items with different features, and where previous competitions resulted in price inversions. This new bidding method would apply to enteral pumps.
- Revise and expand its methodology for adjusting DMEPOS fee schedule amounts for similar items with different features using information from competitive bidding programs.
- Require a bidding entity to obtain a $100,000 bid surety bond for each competitive bidding area (CBA) in which it submits a bid.
- Establish an appeals process for suppliers who receive a breach of contract notice from CMS.
- Codify in the regulations the statutory requirement that a contract will not be awarded to a bidding entity unless the entity satisfies applicable state licensure requirements.

CMS is soliciting feedback on the accessibility of DME for people dually eligible for Medicare and Medicaid, as well as potential regulatory or legislative reforms that could address Medicare and Medicaid DME program misalignments. Interestingly, this request for information appears to be limited to DME, and does not reference other DMEPOS items.
In addition, CMS posted the competitive bid rates and it appears that the competitive bidding rates for NPWT have decreased. Comments on the proposed rule are due by August 23, 2016.

**Home Health PPS**

**A. NPWT**

Background: Section 1895 of the Act requires that the HH PPS includes payment for all covered home health services. Section 1814(k) of the Act specifically excludes DME from the national, standardized 60-day episode rate and consolidated billing requirements. DME continues to be paid outside of the HH PPS. Medical supplies are included in the definition of “home health services” and the cost of such supplies is included in the national, standardized 60-day episode payment amount. Supplies are classified into two categories, specifically:

- **Routine**: Supplies used in small quantities for patients during the usual course of most home visits; or
- **Non-routine**: Supplies needed to treat a patient’s specific illness or injury in accordance with the physician’s plan of care and meet further conditions.

The law requires that all medical supplies (routine and non-routine) be provided by the HHA while the patient is under a home health plan of care. A disposable NPWT system would be considered a non-routine supply for home health.

Consolidated billing requirements ensure that only the HHA can bill for home health services, with the exception of DME and therapy services provided by physicians, when a patient is under a home health plan of care. The types of service most affected by the consolidated billing edits tend to be non-routine supplies and outpatient therapies, since these services are routinely billed by providers other than HHAs, or are delivered by HHAs to patients not under home health plans of care.

As provided under section 1834(k)(5) of the Act, a therapy code list was created based on a uniform coding system (that is, the HCPCS) to identify and track these outpatient therapy services paid under the Medicare Physician Fee Schedule (MPFS). The list of therapy codes, along with their respective designation, can be found on the CMS Web site, specifically at [http://www.cms.hhs.gov/TherapyServices/05_Annual_Therapy_Update.asp#TopOfPage](http://www.cms.hhs.gov/TherapyServices/05_Annual_Therapy_Update.asp#TopOfPage). Two of the designations that are used for therapy services are: “Always therapy” and “sometimes therapy.” An “always therapy” service must be performed by a qualified therapist under a certified therapy plan of care, and a “sometimes therapy” service may be performed by physician or a non-physician practitioner outside of a certified therapy plan of care. CPT codes 97607 and 97608 are categorized as a “sometimes” therapy, which may be performed by either a physician or a non-physician practitioner outside of a certified therapy plan of care.

For patients under a home health plan of care, payment for routine and non-routine supplies are included in the episode payment amount. A disposable NPWT system is currently considered a non-routine supply and
thus payment for the disposable NPWT system is included in the episode payment amount. The Consolidated Appropriations Act of 2016 requires a separate payment to a HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Section 1834(s)(2) of the Act defines an applicable device as a disposable negative pressure wound therapy device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy used in lieu of a conventional NPWT DME system.

As required by the Consolidated Appropriations Act of 2016 (Pub. L. 114-113), the separate payment amount for NPWT using a disposable system is to be set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the Level I Healthcare Common Procedure Coding System (HCPCS) code, otherwise referred to as Current Procedural Terminology (CPT-4) codes, for which the description for a professional service includes the furnishing of such a device. The OPPS rate for NPWT actually went up so we do not oppose this at this time.

Under the OPPS, CPT codes 97607 and 97608 (APC 5052—Level 2 Skin Procedures), include furnishing the service as well as the disposable NPWT device.

Proposal: CMS is proposing that for instances where the sole purpose for a HHA visit is to furnish NPWT using a disposable device, Medicare will not pay for the visit under the HH PPS. Instead, they propose that since furnishing NPWT using a disposable device for a patient under a home health plan of care is to be paid separately, based on the OPPS amount, which includes payment for both the device and furnishing the service, the HHA must bill these visits separately under type of bill 34x along with the appropriate HCPCS code (97607 or 97608) and NOT 32x.

If NPWT using a disposable device is performed during the course of an otherwise covered HHA visit (for example, while also furnishing a catheter change), CMS proposes that the HHA must not include the time spent furnishing NPWT in their visit charge or in the length of time reported for the visit on the HH PPS claim (type of bill 32x). Providing NPWT using a disposable device for a patient under a home health plan of care will be separately paid based on the OPPS amount relating to payment for covered OPD services. In this situation, the HHA bills for NPWT performed using a disposable device under type of bill 34x along with the appropriate HCPCS code (97607 or 97608). Additionally, this same visit should also be reported on the HH PPS claim (type of bill 32x), but only for the time spent furnishing the services unrelated to the provision of NPWT.

Moreover, since the CPT codes (97607 and 97608) are considered “sometimes” therapy codes, NPWT using a disposable device for patients under a home health plan of care can be performed, in accordance to State law, by a registered nurse, physical therapist, or occupational therapist and the visits would be reported on the type of bill 34x using revenue codes 0559, 042X, 043X. The descriptions for CPT codes 97607 and 97608 include performing a wound assessment. As such, under the proposed rule, CMS believes that it would only be appropriate for these visits to be performed by a registered nurse, physical therapist, or
occupational therapist as defined in § 484.4 of the Medicare Conditions of Participation (CoPs). The amount paid to the HHA by Medicare will be equal to 80 percent of the lesser of the actual charge or the payment amount as determined by the OPPS for the year.

B. HH QRP Update
CMS is proposing to adopt for the CY 2018 payment determination four measures to meet the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. Three of these measures are resource-based and calculated using Medicare claims. The fourth measure is assessment-based and is calculated using Outcome and Assessment Information Set (OASIS) data. The proposed measures are as follows:

• All-condition risk-adjusted potentially preventable hospital readmission rates,
• Total estimated Medicare spending per beneficiary,
• Discharge to the community, and
• Medication reconciliation.

C. Home Health Value Based Purchasing Model

Under the CY 2017 Home Health Prospective Payment System proposed rule, in addition to providing an update on the progress towards developing public reporting of performance under the HHVBP Model, CMS proposes the following changes and improvements related to the HHVBP Model:

• Calculate benchmarks and achievement thresholds at the state level rather than the level of the size-cohort and revise the definition for "benchmark" to state that benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period calculated for each state;
• Require a minimum of eight HHAs in a size-cohort;
• Increase the timeframe for submitting New Measure data from seven calendar days to fifteen calendar days following the end of each reporting period to account for weekends and holidays;
• Remove four measures (Care Management: Types and Sources of Assistance, Prior Functioning ADL/IADL, Influenza Vaccine Data Collection Period, and Reason Pneumococcal Vaccine Not Received) from the set of applicable measures;
• Adjust the reporting period and submission date for the Influenza Vaccination Coverage for Home Health Personnel measure from a quarterly submission to an annual submission; and
• Add an appeals process that includes the existing recalculation process and adds a reconsideration process.

CMS is seeking comments which are due August 26, 2016
Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures; Proposed Rule

The Medicare program includes multiple administrative appeals processes that must be exhausted before a provider or beneficiary can sue to recover benefits. As you are all aware, these processes have been hampered by backlogs and significant delay in adjudication. On July 5, the Centers for Medicare & Medicaid Services (CMS) published its proposed changes to the Medicare appeals processes in order to tackle the “unprecedented and sustained increase in the number of appeals.”\(^1\) The proposed regulations make structural and procedural modifications to major components of the Medicare appeals systems. This is the latest in a series of administrative actions designed to reduce the volume of appeals and alleviate the significant backlog and delays with pending appeals.

Lynn Snyder and her colleagues at Epstein, Becker and Green will be further discussing this proposed rule during the complimentary compliance webinar being offered on August 17, 2016

Overview of Current Administrative Appeals Process

There are several levels of review that must be followed to resolve disagreements regarding Medicare coverage and payment determinations, eligibility and entitlements, and enrollment penalties and premiums.

- **Levels 1 and 2** (administered by Medicare contractors, MAOs, Medicare plans, Medicare contractors, and plan sponsors): Redeterminations and reconsiderations are the first levels of review for aggrieved Medicare beneficiaries, Medicare providers and suppliers, Medicare plans, Medicare Advantage Organizations (MAOs), and Medicaid state agencies.

- **Level 3 (OMHA)**: Redeterminations and reconsiderations may next be appealed to an Administrative Law Judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS). The decision is “final” if OMHA affirms a dismissal of a request for reconsideration.

- **Level 4 (DAB)**: Except for a decision affirming a dismissal of a request for reconsideration, OHMA’s decisions may be reviewed by the Medicare Appeals Council (Council) within the Departmental Appeals Board (DAB).

Absent extraordinary circumstances, each step in the administrative review process must be completed before judicial review is permitted.

Proposed Changes

The proposed changes are intended to increase consistency in the decision-making process, expand the pool of available adjudicators to increase OMHA’s capacity, and improve the efficiency of the appeals process.

To increase consistency in decisions at all levels of appeal, the Proposed Rule grants the Chair of the DAB the power to designate a determination of the Council as having precedential value. Precedential decisions
are binding on all levels of HHS and CMS. The proposed regulations provide that the legal analysis and interpretation of Medicare provisions of a precedential decision must be followed in future determinations and appeals. The Proposed Rule also would require precedential decisions to be published in the Federal Register.

To expand the pool of available OMHA adjudicators, CMS proposes to permit non-ALJ attorneys to adjudicate certain issues during the appeals process. For instance, attorney adjudicators would review “paper only” appeals, handle certain remands, and conduct reviews of dismissals by Qualified Independent Contractors and Independent Review Entities. The Proposed Rule notes that “attorney adjudicators,” which are employed attorneys at OMHA, would be authorized to review the record, identify issues, and make necessary findings of fact and conclusions of law when the regulations or the enabling legislation do not require an actual ALJ hearing.\(^2\)

To streamline the administrative appeals process, the agency proposes specific procedural modifications to simplify proceedings, clarify certain areas of regulations, and create process efficiencies. Among others, these changes include:

- Revising the amount in controversy such that it is more closely aligned with the actual amount in dispute (i.e., using Medicare’s allowed amount instead of the provider’s charge);
- Limiting the number of entities that may participate or be a party at hearings (i.e., CMS or contractor);
- Clarifying when appeal to the Council is available;
- Eliminating unnecessary or duplicative administrative steps and streamlining submission of evidence;
- Facilitating communication through conferences among the parties and permitting correspondence via telephone and email;
- Developing processes for certain types of common issues (i.e., statistical sampling and extrapolating);
- Specifying the type of information that must be submitted during each step of the proceedings; and
- Establishing time frames for adjudicating appeals and remands from the Council.

Comments on the appeals proposed rule are due **August 29, 2016**.

**Medicare Physician Fee Schedule**

While we are still reviewing the Medicare Physician Fee Schedule, we have identified several issues that we think you will be interested in.

**A. Misvalued codes**

In the proposed rule, CMS states that they understand that therapy specialty organizations have pursued the development of coding changes through the CPT process for their modality and procedures services. While they understand that, in some cases, it may take several years to develop appropriate coding revisions. As a result, CMS in the meantime, CMS is seeking information regarding appropriate valuation for the existing codes.
Of the codes identified as Potentially Misvalued Codes Through High Expenditure By Specialty Screen – include:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>97032</td>
<td>Electrical stimulation</td>
</tr>
<tr>
<td>97035</td>
<td>Ultrasound therapy</td>
</tr>
</tbody>
</table>

B. Global Packages

There is a lot of information contained in the proposed rule related to the Global packages. In the past the Alliance has commented on proposed provisions to the global packages. In previous rulemaking, CMS discussed the problems with accurate valuation of 10- and 90-day global packages and developed a policy to transform all 10-day and 90-day global codes to 0-day global codes in CY 2017 and CY 2018 respectively, to improve the accuracy of valuation and payment – which we did not support. Subsequently, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was passed, prohibiting the Secretary from implementing the policy. Instead, MACRA requires CMS to collect data to value surgical services and develop, through rulemaking, a process to gather the information needed to value surgical services from a representative sample of physicians, and requires that the data collection begin no later than January 1, 2017. MACRA authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information until the required information is reported. Finally, MACRA requires that beginning in 2019, CMS must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS.

CMS is proposing a three-pronged approach to collect timely and accurate data on the frequency of and inputs involved in furnishing global services, including:

1. Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services.
2. A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks.
3. A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.
CMS modified their contract with RAND to include the development of G-codes that could be used to collect data. RAND recommended a set of time-based, post-operative visit codes that could be used for reporting care provided during the post-operative period. The recommended codes are distinguished by the setting of care and whether they are furnished by a physician/NPP or by clinical staff. All codes are intended

CMS has stated in the proposal that the statute allows them to withhold payment of up to 5 percent of the payment for services on which the practitioner is required to report until the practitioner has completed the required reporting; however, CMS is not proposing to implement this option at this time. That said, if CMS finds that compliance with required claims-based reporting is not acceptable, they would consider in future rulemaking imposing the 5 percent penalty.

Furthermore, CMS also proposes to review 83 codes for 0-day global services that typically are reported with an evaluation and management (E/M) service with modifier 25 (which allows physicians to be paid for E/M services that would otherwise be denied as bundled).

C. Additional Issues

1. Administered by the Centers for Disease Control and Prevention, the Diabetes Prevention Program (DPP) is aimed at preventing the onset of diabetes in pre-diabetic individuals through the use of a clinical intervention consisting of increased physical activity, dietary changes, and other behavior changes. The Center for Medicare & Medicaid Innovation previously tested this model, and CMS now proposes to permanently expand it to the full Medicare population. Medicare would reimburse Medicare suppliers for providing Medicare DPP services to beneficiaries beginning Jan. 1, 2018. CMS is asking for comment on the program, including the enrollment of providers and suppliers as well as eligibility requirements for beneficiaries.

2. With other notable provisions in the proposed rule, CMS hopes to smooth out a wrinkle that allowed a self-referral physician to levy per-unit rental charges to use space and equipment owned by the physician and leased to the referred facility, and aims to require all Medicare Advantage providers and suppliers to first be screened and enrolled in traditional Medicare.

There are likely other issues contained in the proposed rule that you/your organization is interested. If there are other issues not identified in this summary please let us know. Comments on the physician fee schedule are due September 6
CMS issued the Hospital Outpatient PPS and Ambulatory Surgical Payment System on July 6. This is an initial summary of the multiple issues that are contained in this proposal.

A. Payment of Items and Services Furnished by Off Campus Outpatient Departments or provider based department.

CMS is proposing a number of policies that they believe will improve the quality of care Medicare patients receive. A key proposal in this year’s rule is the implementation of Section 603 of the Bipartisan Budget Act of 2015, which will affect how Medicare pays for certain items and services furnished by certain off-campus outpatient departments of a provider or provider based departments (PBDs). Those identified will not be considered covered outpatient department services for purposes of OPPS payment and shall instead be paid “under the applicable payment system” beginning January 1, 2017. Specifically, CMS has identified Excepted Items and Services – CMS proposes that certain off-campus PBDs would be permitted to continue to bill for excepted items and services under the OPPS. Excepted items and services are:

- All items and services furnished in a dedicated emergency department.
- Items and services that were furnished and billed by an off-campus PBD prior to November 2, 2015.
- Items and services furnished in a hospital department within 250 yards of a remote location of the hospital.

Service Expansions, Relocations, and Changes of Ownership

- Service Expansion in an Excepted Off-Campus PBD – While excepted off-campus PBDs will be paid at OPPS rates for items and services furnished and billed as of November 2, 2015, CMS is proposing that additional items and services beyond those within the clinical families of services furnished and billed prior to that date will not be excepted services.
- Relocation of Excepted Off-Campus PBDs – CMS is proposing that items and services must continue to be furnished and billed at the same physical address of the off-campus PBD as of November 2, 2015, in order for the off-campus PBD to be considered excepted from Section 603 requirements. CMS is proposing that an excepted off-campus PBD will lose its excepted status if it changes location. CMS is requesting comment on whether there should be exceptions to this proposal for extraordinary circumstances that are outside the control of the hospital.
- Changes of Ownership of Excepted Off-Campus PBDs – CMS is proposing that if a hospital has a change of ownership and the new owners accept the existing Medicare provider agreement from the prior owner, the off-campus PBD may maintain its excepted status under the other rules outlined in this regulation.

Applicable Payment System – For CY 2017, CMS proposes the Medicare Physician Fee Schedule (MPFS) to be the “applicable payment system” for the majority of non-excepted items and services furnished in an off-campus PBD. Physicians furnishing such services would be paid based on the professional at the non-facility rate under the MPFS for services which they are permitted to bill. CMS intends for this payment proposal to be a one-year transitional policy while they explore operational changes that would allow an off-campus PBD to bill Medicare for its services under a Part B payment system other than the OPPS beginning in 2018. Provided it can meet all Federal and other requirements, a hospital would have the option of enrolling the non-excepted off-campus PBD as the provider/supplier it wishes to bill in order to meet the requirements of that payment system (such as an ASC or group practice).

For CY 2018, CMS is soliciting comments on regulatory and operational changes that they could make to
allow a non-excepted off-campus PBD to bill and be paid for its non-excepted items and services under an applicable payment system (other than the OPPS). CMS also seeks other comments in implementation of this provision as well.

Wound Care Centers could be impacted by the proposals above.

B. Other issues include:

1. Device pass-through payments are intended to enable access to certain new medical devices that represent a substantial clinical improvement relative to existing diagnostic or therapeutic services. In response to stakeholder requests for greater transparency, in CY 2016, CMS adopted a policy to continue to accept and review device pass-through applications on a quarterly basis but to also include discussions of the preliminary pass-through applications in the next applicable OPPS proposed rule. For CY 2017, CMS includes a discussion of three applications for which preliminary approval has not been granted based upon quarterly review. One of the applications was for maggot therapy for the treatment of wounds.

2. Quality - Update to refine the requirements for the Hospital outpatient quality reporting system (HOQR) and the ambulatory surgical center quality reporting program (ASCQR)
The Hospital OQR program requires hospital outpatient facilities to meet administrative, data collection, and submission, validation, and reporting requirements, or receive a 2 percentage point reduction in their annual payment update.
CMS is proposing to add a total of seven measures to the Hospital OQR program for the CY 2020 payment determination and subsequent years: two claims-based measures, and five Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems survey-based measures.
The rule also would add seven measures to the Ambulatory Surgical Center Quality Reporting Program measure set for the CY 2020 payment determination and subsequent years.

It appears, of the 7 proposed measures, there are probably 2 that a wound center could use, which are the patient surveys of the facilities and staff and whether the patient would recommend the facility.

The Proposed measures in the OPPS regulation:

**Claim based measures**

1. OP – 35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
2. OP – 36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687)

**Survey based measures**

1. OP – 37a: OAS CAHPS – About Facilities and Staff;
2. OP – 37b: OAS CAHPS – Communication about Procedure;
3. OP – 37c: OAS – CAHPS – Preparation for Discharge and Recovery
4. OP – 37d: OAS CAHPS – Overall Rating of Facility;
Furthermore, CMS proposes to publicly display data on the Hospital Compare website, or other CMS website, beginning with the CY 2018 payment determination. According to the proposal, hospitals will have approximately 30 days to preview their data.

3. Removal of the HCAHPS pain management from the hospital outpatient value based purchasing program
The Centers for Medicare and Medicaid Services is proposing to remove the HCAHPS survey pain management questions from the hospital payment scoring calculation hospitals. However would continue to use the questions to survey patients about their in-patient pain management experience, but these questions would not affect the level of payment hospitals receive.

4. E/M – Modifier 25 - The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) have reviewed the use of Modifier 25 to unbundle payments for evaluation and management (E/M) services when a procedure is performed. In the 2017 Medicare Physician Fee Schedule Proposed Rule, CMS has identified 83 target codes for review. Modifier 25 should only be used when services are provided beyond those considered to be part of the procedure performed. The over use of Modifier 25 was noted by the OIG in 2005. In the 2005 report the OIG found that 35% of the claims using Modifier 25 did not meet the billing guidelines, resulting in improper payments. The specific listing of the 83 target codes in the 2017 Proposed Rule could mean increased auditing of the use of Modifier 25. One of the codes listed includes: G0168 – Wound Closure utilizing tissue adhesives only

5. Device Intensive Procedures - CMS proposes to assign device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40% regardless of the APC assignment. That is, CMS would look to the HCPCS/CPT level rather than calculate the device offset at the APC level. CMS also proposes to base payment for very low-volume device-intensive APCs (fewer than 100 total claims) on the median cost rather than the geometric mean

6. Packaging - CMS proposes to apply its conditional packaging policy at the claim level instead of based on the date of service. CMS expects this change would increase conditional packaging, since packaging would occur whenever a conditionally packaged item or service is reported on the same claim as a primary service regardless of the date of service.

7. The following represents the proposed payment and APC categories for some of the wound care related items/procedures:
Please note that the rates for NPWT have gone up. Moreover, the rates for some CTPs have gone down significantly while others have seen an increase. The fluctuation in CTP rates is causing some concern.

Comments on the hospital outpatient PPS proposed rule are due September 6
Action Plan for Further Improvement of Nursing Home Quality

Just to keep our members apprised, on May 17, the Centers for Medicare & Medicaid Services (CMS) released its new Action Plan for Further Improvement of Nursing Home Quality (Action Plan). The Action Plan is CMS’ strategic plan for nursing homes that is published every four years. The 2016 Action Plan sets forth five coordinated sets of actions (Action Plan Elements) and describes in detail how CMS has been, and plans to continue, making progress on each element of the Action Plan.

The five Action Plan Elements are as follows: (1) enhance consumer awareness and assistance; (2) strengthen survey processes, standards, and training; (3) improve enforcement activities; (4) promote quality improvement; and (5) create strategic approaches through partnerships. Most of the action items are either ongoing or scheduled to occur in 2016. The paragraphs below highlight some specific activities and programs discussed in the Action Plan, organized by the five Action Plan Elements.

**Enhance Consumer Awareness and Assistance**

CMS is enhancing its five-star rating system, which assigns a star rating to each nursing home facility based upon three domains: (1) the past approximately three years of health inspections; (2) selected quality measures; and (3) staffing. CMS is currently evaluating additional quality measures for nursing home hospitalization, discharge to community, and functional status improvement. Staffing has historically been self-reported; however, beginning July 1, CMS will collect its staffing data from quarterly payroll-based data.

**Strengthen Survey Process, Standards, and Training**

CMS soon will issue final regulations revising and updating the State Operations Manual (SOM), Appendix PP Interpretive Guidance. In anticipation of these new participation requirements, CMS has issued tools to prepare nursing homes, including advance copies of Survey and Certification policy memos, satellite broadcasts, and other training tools.

CMS has been refining the Quality Indicator Survey (QIS) survey approach while continuing to evaluate the QIS survey process in comparison to the traditional survey process. CMS intends to combine the strengths of both the QIS and the traditional processes into a unified survey methodology to be implemented nationwide.

There is expanded access to web-based training for surveyors and CMS regional offices. Additionally, CMS is strengthening the consistency and quality of nursing home complaint intake and investigations at both the state survey agency and regional office levels.

Another area of focus for CMS is health care associated infections (HAIs). Surveyors are receiving additional training on HAIs, and CMS is partnering with the Centers for Disease Control and Prevention to address nursing home HAIs. Provider-focused HAI trainings may be made available in the future. CMS has published policy guidance to address specific processes that pose an infection control risk (i.e., reprocessing single-use devices and laundry) and intends to issue future policy guidance on urinary tract infections in nursing homes.
CMS regional office oversight of the state survey agencies will be increased in order to ensure that the State Performance Standards System for survey quality is being properly and consistently effected.

*Improving Enforcement Activities*

CMS has developed a Nursing Home Enforcement Strategic Action Plan that focuses on transparency and consistency in the application of enforcement remedies nationwide. Specifically, key action items include impending revisions to Chapter 7 of the SOM, which will expand the circumstances where civil monetary penalties are imposed, the publication of new online Nursing Home Enforcement Reports, new guidance regarding immediate jeopardy citations, and initiatives to monitor and improve special focus facility outcomes.

*Promote Quality Improvement*

CMS is updating the Minimum Data Set (MDS) 3.0 quality measures, expanding a five-state pilot for MDS-focused surveys, and standardizing MDS assessment tools and quality measures. There will be ongoing quality assurance and performance improvement (QAPI); however, the much-anticipated QAPI final rule still has yet to be issued. CMS has, however, developed tools and supports for nursing homes and surveyors designed to encourage a systems approach to improving quality and decreasing adverse events. Other CMS quality improvement efforts include the development of a five-state pilot for a dementia care-focused survey and its subsequent expansion.

*AB MAC Draft Policies*

In addition to the multitude of CMS proposed regulations, the AB MAC contractors have also issued a couple of draft LCDs of interest to our members.

Noridian issued a draft LCD for HBOT. There are multiple issues within the language of the draft policy which need to be addressed. The Alliance has drafted comments and will be circulating these comments to our members for their feedback. Noridian comments are due **August 8, 2016**

CGS issued a draft LCD for CTPs. There are multiple issues within the language of the draft policy which need to be addressed as well. The Alliance has drafted comments and will be circulating these comments to our members for their feedback. CGS comments are due **August 8, 2016**