Provider Roundtable

June 25, 2018

Avera Health
(IA, MN, NE, ND, SD)

Atrium Health
(NC, SC)

Baptist Health South Florida
(FL)

Community Hospital
Anderson (IN)

Franciscan Missionaries of
Our Lady Health System
(LA)

Hardin Memorial Hospital
(KY)

Hartford Hospital
(CT)

Kaiser Permanente, Southern
California Permanente
Medical Group
(CA)

SSM Health
(IL, MO, OK, WI)

University of Pittsburgh
Medical Center
(PA)

Vanderbilt University
Medical Center (TN)

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-81850

Re: CMS-1694-P

Dear Ms. Verma,

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the FY 2019 Inpatient Prospective Payment System (IPPS) Proposed Rule, as published in the *Federal Register*.

The Provider Roundtable (PRT) includes representatives from 10 different health systems, serving patients in 28 states. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services under CMS reimbursement systems, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual IPPS policymaking process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Attachment A.**

Please feel free to contact me at 765-298-2110 or via email at: *trinker@ecommunity.com*.

Sincerely,

Terri Rinker, MT (ASCP), MHA (Chair)
PRT Chair and
Revenue Cycle Director
Community Hospital Anderson
Anderson, IN

PRT Recommendations

In the comment letter that follows, the PRT makes recommendations on these specific issues:

1. Proposed Changes to MS-DRGs Subject to Post-Acute Transfer Policy and MS-DRG Special Payment Policies
2. Proposed Revisions of Hospital Inpatient Admission Orders Documentation Requirements under Medicare Part A
3. Proposed Revisions Regarding Physician Certification and Recertification of Claims
4. Requirements for Hospitals to Make Public a list of Their Standard Charges via the Internet
5. Alternative Considered for a Potential Change to the CCRs used for Outliers, New Technology Add-on Payments, and Payments to IPPS-Excluded Cancer Hospitals for Chimeric Antigen Receptor (CAR) T-cell Therapy
6. Laboratory DOS Exception for Molecular Pathology and Advanced Diagnostic Lab Tests
7. Quality and Value-based Purchasing Program Changes

1. Proposed Changes to MS-DRGs Subject to Post Acute Transfer Policy and MS-DRG Special Payment Policies

The PRT understands that CMS is proposing to add transfers to hospice care to the post-acute transfer policy. We are concerned about the situations related to clinical practice of patients being transferred from a community hospital to a tertiary type hospital for treatment prior to a confirming a terminal diagnosis. This 3-day rule would implement a requirement that a patient must have a minimum acute hospital stay of three days prior from the same acute hospital to transfer to a hospice unit in order to trigger the post-acute DRG transfer policy.

- The PRT recommends a required 3-day acute hospital stay for patients diagnosed with sepsis who are transferred to hospice prior to triggering the post-acute transfer policy.

2. Proposed Revisions of Hospital Inpatient Admission Orders Documentation Requirements under Medicare Part A

In the 2014 IPPS/LTCH PPS final rule, CMS adopted a set of policies referred to as the "2 midnight" payment policy. As part of the adoption, CMS codified through regulations at 42 CFR 412.3 the policy that a beneficiary becomes a hospital inpatient if admitted formally pursuant to the order of a physician or another qualified practitioner in accordance with the hospital conditions of participation. CMS further required that a written inpatient admission order be present in the medical record as a condition of Medicare Part A payment. In response to stakeholder comments, CMS advised that when the order to admit is defective or missing, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner can clearly be derived from the medical record, medical review contractors were provided with discretion to determine that this information constructively satisfies the requirement of the presence of a written hospital inpatient admission order.

As CMS has gained experience with the policy, it has come to the Agency's attention that some otherwise medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders, such as missing signatures or co-signatures and signatures occurring after discharge. CMS acknowledges that these discrepancies have occasionally been the primary reason for payment denials. In seeking to reduce unnecessary administrative burden,

CMS has concluded that if the hospital is operating in accordance with the conditions of participation, medical review should focus on whether the inpatient admission was medically reasonable and necessary as the occasional inadvertent signature documentation issues are unrelated to the medical necessity of the inpatient stay. The Agency noted that it was not their intent that the admission order documentation requirements finalized in the 2014 IPPS/LTCH PPS final rule should, by themselves, lead to denial of payment for otherwise medical reasonable inpatient stays.

To remedy this situation, CMS is proposing to revise the inpatient admission order policy to no longer require a written order to be present in the medical record as a specific condition of Medicare Part A payment. If other available documentation, such as the physician certification statement when required, progress notes, or the medical record as a whole supports that all the coverage criteria (including medical necessity) are met, and the hospital is operating in accordance with the hospital conditions of participation, CMS believes it is no longer necessary to also require specific documentation requirements of inpatient admission orders as a condition of Medicare Part A payment. The regulations at 42 CFR 412.3(a) will be revised to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital services under Medicare Part A.

The PRT applauds CMS for taking action to remove an unnecessary administrative burden on physician and hospital providers. We are in full support of the proposal to remove the language stating that a physician order must be present in the medical record and supported by the physician admission and progress notes in order for the hospital to be paid for hospital services under Medicare Part A.

Following implementation of the "2 midnight" policy, hospitals have put in place processes to review and approve billing of inpatient hospital stays. These self-audits have led to instances where a medically reasonable and necessary inpatient admission was not approved for billing simply because the order was not signed before discharge. All other documentation in the medical record may have fully supported the inpatient status; however, the hospital "self-denied" the claim due to a technicality tied to the order. Removal of the language from 42 CFR 412.3(a) will provide clarification to reviewers, both internal and external.

In the discussion of the rationale for the change, CMS acknowledges that the entire medical record should be considered when determining whether coverage criteria, including medical necessity, has been met. CMS notes that specific sources of this documentation include the physician certification statement when required, progress notes, or the medical record as a whole. The PRT agrees with this assessment. The PRT is concerned, however, that if the guidance regarding consideration of the entire medical record as support for coverage is not codified, reviewers will not adhere to this guidance. Past experience supports this concern; as CMS notes, when the changes were made as a result of the 2014 implementation of the 2midnight policy, CMS provided guidance that in situations where the order was deficient, medical reviewers had the discretion to determine whether other information in the record satisfied the requirement that a written order be present. Experience has proven, however, that reviewers have not always heeded this guidance and have instead, denied admissions based upon technical issues with the physician order.

The section CMS proposes to revise is 42 CFR 412.3(a). The PRT believes that section 42 CFR 412.3(b) should also be revised. Currently, the regulation states, "The order must be furnished…" By specifying "order" this may imply that a specific document called an order is required, rather than taking into account the other documentation that may support the intent and medical necessity. In 42 CFR Subpart

B Certification and Plan Requirements, Section 424.11(b), the regulations related to the physician certification state, *"The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form."* This codifies that there is not specific form for the certification statements. The PRT recommends that similar language be added to 42 CFR 412 to specify that "the physician order for inpatient admission, as a condition of payment, may take the form of a specific order or may be derived from other information in the medical record, such as the physician certification, progress notes, or the medical record as a whole."

3. Proposed Revisions Regarding Physician Certification and Recertification of Claims

The PRT fully supports CMS' ongoing initiatives to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome. CMS has proposed revisions to 42 CFR 424.11(c), which currently states that if the information needed to supply the required certification or re-certification statement is contained in the medical record, such as physicians' progress notes, the information does not need to be repeated on a specific form. The current regulation goes on to say, there should be a statement to indicate where the information is to be found. CMS proposes removing the language requiring a statement to indicate where the information may be found. The PRT fully supports CMS proposed revision and applauds the agency's efforts to reduce unnecessary administrative burdens.

4. Requirements for Hospitals to Make Public a list of Their Standard Charges via the Internet

The Provider Round Table (PRT) appreciates the CMS for continuing to pursue the discussion on pricing transparency and eliciting feedback from the stakeholders in this year's Inpatient Proposed Rule. The PRT has several comments regarding CMS' proposals as well as responses to the questions posed by CMS concerning price transparency.

Concerning Out-of-Network Co-Insurance

The PRT acknowledges that patients do at times receive bills for higher out-of-network co-insurance and that these may be from various physician groups (e.g.: anesthesiologists, radiologists, pathologists, emergency department physicians) who are independent medical groups and legally separate from hospitals. Hospitals solely negotiate for the entities within their legal structure and do not have the ability to negotiate on behalf of separate legal entities nor to ensure these healthcare providers accept the same insurance plans as the hospital accepts. Rather, we believe it is incumbent upon the insurance companies to inform and educate their customers on what is in-network and out-of-network under their particular plans. In fact, a provision of the Affordable Care Act specifies the requirements of insurance companies to disclose liabilities by participating and non-participating providers. We note that an example of this is published by CMS and can be viewed at https://www.cms.gov/CCIIO/Resources/Files/Downloads/sbc-sample.pdf. Furthermore, Medicare Part A and Part B beneficiaries are not impacted by networks, so should CMS desire additional disclosure this must be addressed directly with the Part C plans and not through requirements of hospitals. CMS should explore the transaction set standards of the Administrative Simplification Act as a means to standardize what insurers should be required to provide for price transparency.

Posting "Standard Prices"

The PRT knows how important state rights are to this Administration. The issue of price transparency is one that individual states have and continue to address. Most states already require some method of price transparency. The National Conference of State Legislatures has provided a web page that addresses pricing transparency and provides a summary of enacted cost transparency legislation provided by state. Please see the link below:
http://www.ncsl.org/research/health/transparency-and-disclosure-health-costs.aspx#Legislation

It appears that currently 29 states have provided some information for beneficiaries regarding pricing transparency including recent legislation passed in New Jersey. Since insurance design is governed by state law, it is logical that price transparency also be determined by state law. As evidenced by many other of its proposed 2019 policies, CMS is very interested in decreasing administrative burden stemming from Medicare policies and the PRT believes that price transparency is another area to relegate to the individual states.

The PRT agrees with the CMS statement "*We are concerned that chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay*." This is one reason we are perplexed by the CMS proposal to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format. While there is no definition of "standard charges", we assume that a reasonable interpretation is posting the chargemaster charges. Since the chargemaster or a list of standard charges from the chargemaster does not provide the beneficiaries with the information they are requesting or needing, the availability of this list online will only create more confusion and frustration on the beneficiaries' part. As CMS knows, the beneficiary liability for covered Part A and Part B services is strictly defined by CMS and participating hospitals must adhere to what CMS determines under its respective payment systems to be the beneficiary portion.

Alternatively, for Part C and other commercial insurances, each insurer is in the best position to provide the beneficiary with the most accurate information they need based on what is included in their individual plan, the discounts negotiated with in-network providers in the beneficiary's market and the year-to-date out-of-pocket payments already made by the beneficiary.

Defining standard charges

Concerning CMS' proposal to create a definition of "standard charges", the PRT notes that there is already a CMS definition of charges which is found in the Provider Reimbursement Manual, Part 1, Section 2202.4 and is quoted below:

"Charges refer to the rates established by the provider for services rendered. Charges should be related consistently to the costs of the services and uniformly applied to all patients, whether inpatients or outpatients. All patients' charges used in the development of apportionment ratios should be recorded at the gross value (i.e., charges before the application of allowances and discounts deductions)."

Hospital charges are tied to CMS' requirement for hospital cost reporting. Hospital charges must follow the requirements of the definition of charges and cost reporting principles. Because hospital charges are set based on the individual hospital's underlying costs, they vary significantly. Requiring hospitals to post these charges that have no bearing to what patients owe may result in external pressures due to media attention to change charges that would undermine CMS' rate setting process through the cost report.

In addition, hospital charges are becoming increasingly irrelevant to payments due to the increase in bundled (episodic) payments for outpatient procedures and MS-DRG payments for inpatient stays. The list of charges from the chargemaster will not assist the beneficiary in understanding what amount they are responsible for paying. Defining standard charges to be some representation of average or median co-insurance and deductibles would also be meaningless to individual beneficiaries because it would not apply to their circumstances. Finally, this information would not assist them in choosing a provider, even one that may be less costly for the beneficiary out-of-pocket. The information becomes useful and actionable by beneficiaries only with individualized patient financial counseling, tools and information provided by insurers.

Many hospitals already have tools in place that provide the prospective patient with an estimate of their hospital related costs. They also have financial counselors available to assist patients with their estimates, bill, insurance questions and financial assistance. Until this proposal, CMS considered hospitals as meeting their obligation to post charges by the alternative of posting a telephone number for patients to call with questions about pricing of services. Furthermore, tax exempt hospitals must also meet the IRS Section 501(r) requirements concerning financial assistance and making patients aware of financial assistance and financial counseling.

Some suggestions the PRT offers for improvements in pricing transparency include:

- Holding insurance plans responsible for educating and informing their members on the out-of-pocket costs in advance of elective services, comparing across sites of care as well as in-network and out-of-network providers. As previously stated, insurers are in the best position to assist their members with this information, as each policy contract has coverage and clauses that are unique. They have the most current information on where the member stands with respect to their deductibles and out-of-pocket maximums as well as which services are covered and which providers near the beneficiary are in- and/or out-of-network.
- Continuing to require hospitals to publicize how and whom patients seek price estimates and financial counseling.
- Work with stakeholders such as the Healthcare Financial Management Association (HFMA) to investigate and publish best practices currently in place at various hospitals around the country for financial counseling.

We strongly believe publishing hospital charges in a machine-readable format available on the internet will not meet the needs of the patients nor will it address the challenges CMS has outlined in the proposed rule. More important, this mandate will further confuse and frustrate patients as they navigate the healthcare system to determine their out of pocket costs. CMS should leave any further legislation or mandates to individual states while continuing to encourage hospitals to improve financial counseling; however, insurers should be held accountable through Administrative

Simplification Act transaction requirements to provide patients with the information in which they are interested.

Additionally, the PRT offers responses to the specific questions posed by CMS in the proposed rule:

QUESTION: *Should "standard charges" be defined to mean: average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together (such as an MS-DRG), as determined by the hospital based on its billing patterns; or the average discount off the chargemaster amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of average contracted rate and the chargemaster? Or is the best measure of a hospital's standard charges its chargemaster?*

The CMS definition of charges can be found in the Provider Reimbursement Manual as cited below:

"Charges refer to the rates established by the provider for services rendered. Charges should be related consistently to the costs of the services and uniformly applied to all patients, whether inpatients or outpatients. All patients' charges used in the development of apportionment ratios should be recorded at the gross value (i.e., charges before the application of allowances and discounts deductions)." <Provider Reimbursement Manual Part 1, Section 2202.4, Charges>

Most hospital charges are set based on the individual Hospital's cost-to-charge ratio. There are many components to this that vary across hospitals. Hospital A's cost-to-charge ratio may be higher in their Cardiology department because they provide both Cath Lab services and non-invasive services in the same department. Hospital B's structure consists of separate Cath Lab and Cardiology departments, with a different cost-to-charge ratio for each based on the services provided. Therefore, if a patient is comparing hospital charges for the same service between Hospital A and Hospital B, there is likely to be a difference and one that can be significant. Comparing charges is much more complex than just offering a "price comparison."

Unfortunately, hospital charges are not as relevant as the public thinks they are. With the increase in bundled (episodic) payments for outpatient procedures and MS DRG payments for inpatient stays, the list of charges from the chargemaster are not going to assist the beneficiary in understanding what amount they are responsible for paying.

Many hospitals already have tools in place that provide the prospective patient with an estimate of their hospital related costs. They also have financial counselors available to assist patients with their estimates, bills and insurance questions.

QUESTION: *What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?*

Patients want to understand what their liability will be for the procedure or inpatient stay. This is driven by the individual patient's coverage through their payer and is unique to each patient at any specific time during the year. As has already been mentioned, there are tools being developed and

refined to assist in this endeavor. Insurers are the best equipped to assist patients with this information based on each patient's individual plan.

QUESTION: *Should health care providers be required to inform patients how much their out-of-pocket costs for services will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations? Should health care providers play any role in helping to inform patients of what their out-of-pocket obligations will be?*

Providers must obtain the information from the insurer and be confident that the information is accurate and up-to-date at the time it was obtained. Because the insurers may receive additional claims prior to the Provider service, this amount most often changes. So the information is often outdated when it is provided to the patient. Insurers are the ones best equipped to handle what a person's out of pocket costs will be for the services in question. They will have the most current information and the details of the plan and their negotiated allowables with the Provider and other Providers both in- and out-of-network.

QUESTION: *Should we require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?*

While each provider know what Medicare will pay it for a service provided to a fee-for-service Part A or Part B beneficiary, it may not have this information for a Medicare Part C plan. For other insurances, healthcare providers do not have the ability to provide patients with this information. They do not have individual plan information, the level of deductibles for each patient, or the coverage guidelines. Hospitals also do not have access to how physicians are going to bill the patients and what insurances they accept. Patients need to be educated on the fact they will be receiving a bill from the hospital for their hospital services and a bill from each physician who sees them at the hospital. Under the current system of physician bills and hospital bills, there is not a way to provide the patient with their total costs. For an inpatient stay, the hospital will be paid one fee (based on the MS-DRG assigned to the case which cannot be established until discharge since there is always the chance there will be complications), and the patient will receive bills from every physician who treats the patient while in the hospital, including consultants whom their primary physician will call in to assist with the case. Many times, a consultant is called in during the admission to address a specific condition; but this is not the time to be talking with a patient or patient's family about how much the provider is going to bill for the service.

QUESTION: *What is the most appropriate mechanism for CMS to enforce price transparency requirements? Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere? How should CMS assess hospital compliance? Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply? Should CMS impose civil money penalties on hospitals that fail to make standard charges publicly available as required by section 2718(e) and (b) of the Public Health Service Act? Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601, et.seq. that applies to issuers that fail to report information and pay rebates related to medical loss ratios, as*

required by sections 2718(a) and (b) of the Public Health Service Act, or would a different framework be more appropriate?

CMS should review what the various state agencies and hospitals are currently doing to comply with pricing transparency. The information on what some of the states are doing has been already provided in a link to the National Conference of State Legislatures. Perhaps eliciting input from the State Hospital Associations would be helpful in understanding the magnitude of the issue and how hospitals are currently dealing with these questions on a state-by-state basis. Gaining an understanding of the best practices already in place would be a first step in developing a sustainable solution to this issue. For the most part Hospitals are attempting to assist their patients in understanding their bills and assisting them with questions on out-of-pocket costs. Hospitals are very in tune to excellent customer service. They understand if a patient is confused and frustrated with the billing process, even if they received exemplary clinical care, they fell short in providing that excellent customer experience. Hospitals are constrained by the information that is available to them.
Penalties should certainly not be applied nor should they be under the purview of CMS.

QUESTION: *How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap? What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best suited to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care? What State-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?*

Hospitals do not have reliable information regarding out-of-pocket costs for patients with Medigap coverage. There are multiple plans that offer Medigap coverage and each plan is different depending upon the premium paid. The higher the premium for the insurance should theoretically provide more coverage. Once again, the insurers are the best prepared to provide patients with the information regarding their out-of-pocket costs for services.

In summary, the PRT recommends:

- CMS look to the individual insurance plans for education and information regarding an individual member's out-of- pocket costs, comparisons across sites of care, as well as in- and out-of-network providers and costs.
- Continuing to require hospitals to publicize the methodology for patients seeking price estimates and financial counseling but not require hospitals to post charges online.
- Work with stakeholders such as the Healthcare Financial Management Association (HFMA) and the State Hospital Associations regarding best practices currently in place.

5. Alternative Considered for a Potential Change to the CCRs used for Outliers, New Technology Add-on Payments, and Payments to IPPS-Excluded Cancer Hospitals for Chimeric Antigen Receptor (CAR) T-cell Therapy

The PRT is pleased to submit our comments on options to better reimburse providers for CAR-T therapy under the IPPS. Several of the PRT members are actively providing or completing the steps to begin providing CAR-T therapy. Uncertainty regarding reimbursement has caused providers to closely

watch the evolution of payment policy and to continually estimate the financial impact of CAR-T therapy with each new case, as hospitals are not able to withstand the significant losses that result under current inpatient reimbursement methodologies. This is true despite the prospects of a new technology add-on payment that is limited to no more than 50 percent of the product costs and/or outlier methodologies that encourage hospitals to have mark-ups based on their overall CCR. If the overall CCR is applied to CAR-T, this would result in multi-hundred-thousand-dollar costs being billed as multi-million-dollar charges. Given CMS' comments on price transparency in this very same proposed rule, the PRT encourages CMS to take the bold steps needed to fairly reimburse CAR-T expense without the concomitant pricing and charge compression issues imposed by current IPPS reimbursement structures. This is extremely important for the first of these breakthrough gene therapies designed not only to treat the condition, but also to hold the promise of eradicating cancer. In the 2019 IPPS proposed rule, CMS invited public comments on alternative approaches to payment for CAR-T cell therapy, and, in fact, discussed the consideration of average sales price (ASP) in the context of the pending new technology add-on payment (NTAP) for the CAR-T products. The PRT strongly believes that an ASP-based payment option, in lieu of the current NTAP payment methodology, would meet several objectives and is very attractive and worthy of serious consideration for numerous reasons.

Because of their extraordinarily high cost, breaking out the CAR-T product cost from the MS-DRG payment for all other patient care services and providing separate payment will benefit CMS. An ASP-based add-on payment to MS-DRG 016, as proposed by CMS, could be updated quarterly and recognize any manufacturer discounts to CAR-T at an earlier point in time rather than during the annual IPPS rulemaking. This approach also brings payment for CAR-T closer between the inpatient and outpatient prospective payment systems, removing any inadvertent financial incentives based on site of care. Payment parity between the inpatient and outpatient settings is an objective that CMS is pursuing independent of CAR-T, but the extraordinary cost of CAR-T makes the need to achieve payment parity between the two programs more compelling. Quarterly updates to the ASP for CAR-T will help ensure fair reimbursement for the product without the risk of overpayment.
CMS already has the infrastructure in place to adopt this payment method for CAR-T as CMS currently uses this approach for blood clotting factors. CMS would require hospitals to itemize the CAR-T product on inpatient claims as is currently required for blood clotting factors to treat hemophilia. The appropriate HCPCS code for the specific CAR-T product should be present on the line item charge on the inpatient claim. Currently, hospitals do not itemize drugs on inpatient claims except in the case of the blood clotting factor for hemophilia patients using revenue code 0636.

The likely revenue code for the CAR-T charge would also be 0636, but the PRT is aware that the National Uniform Billing Committee (NUBC) is considering a unique pharmacy revenue code for the CAR-T product charges; the PRT hopes that this is finalized as we agree with the need for specific revenue codes. If the NUBC were to institute a new specific revenue code soon, CMS would need to be able to adapt the claims processing logic to recognize and accept the new revenue code, along with appropriate HCPCS code, on inpatient claims.

Following the already established requirement for the blood clotting factor add-on payment under IPPS, the inpatient CAR-T claim should be required to have one of the two ICD-10-PCS codes for CAR-T present on the inpatient claim [i.e., XW033C3 *(Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach)* or XW043C3 *(Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach)*] before the ASP-based payment for the CAR-T product is

added to the MS-DRG payment. This methodology has the additional benefit of not adjusting the extraordinary non-labor product cost with IPPS adjustment factors (i.e., wage index, indirect medical education and disproportionate share). The CAR-T product cost should not vary by wage index area or whether or not the hospital is an academic medical center.

The PRT is aware that another reasonable option for applying CMS' proposed CCR of 1.0 would be to require hospitals to report actual acquisition costs on claims using an NUBC Value Code. However, given that this administration values reduced administrative burden for hospitals, using the ASP as a proxy for a CCR of 1.0 avoids administrative burden of a manual process to apply a value code and the actual acquisition cost on claims prior to submission. Because the ASP is based on manufacturers' reporting of average sales for all patients, inpatient and outpatient, we submit it is a good proxy for a CCR of 1.0.

Using ASP for CAR-T as the basis for an add-on payment will avoid inconsistencies between hospitals related to their differing pricing strategies and mark-ups, and should also result in the removal of CAR-T products from any outlier calculations, thus relegating the outlier calculation to all other patient care costs. The PRT does not believe it reasonable for CMS to assume that all hospitals will have a low mark-up on CAR-T and therefore, we do not recommend that CMS merely use the line-item billed charge for CAR-T as the defacto CCR of 1.0 in any payment strategy. The PRT believes using the ASP for an add-on payment to the MS-DRG will provide accurate and specific payment for the product and for only those cases where the drug is actually used. This is in contrast to a payment approach that merely increases the MS-DRG weight (such as MS-DRG 016) where other non-CAR-T cases are grouped. Furthermore, it is our contention that the development of a separate ASP-based payment as an add-on to the MS-DRG payment for patient care costs will protect the integrity of the MS-DRG payment structure.

Should CMS not be persuaded to use its authority to create an ASP-based add-on payment for CAR-T, our second recommended alternative approach is one that would still enable CMS to achieve site neutrality payment and allow equitable recognition of the full CAR-T drug cost.
This option would be to move forward with the proposed realignment of ICD-10-PCS procedure codes XW033C3 and XW043C3 to MS-DRG 016, but with one significant change: CMS would instruct providers to code and bill for the genetically modified autologous cells using the product-specific HCPCS at the time of the outpatient encounter to extract the cells from the patient (i.e., at the time the cells are sent to the manufacturer to begin the genetic engineering process). Extraction of cells from the patient most often occurs during an outpatient encounter several weeks in advance of the inpatient stay for the administration of the modified cells. In effect this would allow the cell bioengineering to be paid at ASP+6% under the OPPS and would be in lieu of NTAP payments under the IPPS. This methodology would resolve issues of budget neutrality within the IPPS since payment would be under Part B. In addition, this methodology would address CMS' stated concerns over the "redistributive effects away from core hospital services over time toward specialized hospitals". The PRT believes that ultimately, this option would foster better access for patients.

The PRT has asked CMS' HCPCS division to remove language from the current Q-codes for CAR-T [Q2040 – Kymriah, Q2041 – Yescarta] and disassociate the terminology "including leukapheresis and dose preparation procedures" from the code descriptors. If CMS were to move forward and agree to public comment, the change to the HCPCS code descriptors should have no bearing on the

appropriateness of reporting all individual clinical services performed on different dates of service in different settings (i.e., outpatient versus inpatient). CMS can still associate payment for the CAR-T product at the time of cell collection with the revised CAR-T product HCPCS code by announcing this as a payment policy.

If the current Q-code descriptors are perpetuated, the logical conclusion is that the Q-code should be billed on the claim for the date of service that initiates the "bundled episode" (i.e., an outpatient encounter for the collection of the cells) regardless in which setting the ultimate infusion of the engineered cells occurs.

Finally, to undergird appropriate data collection and reporting for future rate-setting and cost-reporting purposes, we encourage CMS to proactively engage with the NUBC to develop and establish new/unique UB-04 revenue codes for the reporting of CAR-T associated products and services, as well as creating (at minimum) a dedicated cost center for the mapping of the genetically modified cell products. We also ask CMS to consider establishing a 20th IPPS cost grouping whereby CAR-T expenses and revenues may be isolated for accurate rate setting from the outset. The future promises to present additional scenarios that are similar as additional genetic engineering treatments are created; isolating these specific therapies now will benefit payment processes going forward. As CMS knows, asking hospitals to change their accounting practices is difficult once accounting practices are already in use.

6. <u>Laboratory DOS Exception for Molecular Pathology and Advanced Diagnostic Lab Tests</u>

The PRT is aware that CMS did make a proposal or solicit comments on this topic in the FY 2019 IPPS proposed rule on this topic however, in the CY 2018 OPPS Final Rule, CMS stated at 82 FR 52538 "…we intend to continue studying this issue and, if warranted, consider changes to the laboratory DOS policy for laboratory tests performed on specimens collected during an inpatient hospital stay in future rulemaking." We believe that it was an unintended oversight to not discuss this topic in the FY 2019 IPPS proposed rule and we ask that CMS consider proposing a change to the DOS policy for these tests that is consistent between hospital inpatients and outpatients.

The PRT supports the new outpatient DOS exception for these tests, and we note that it is very important that the new DOS exception which applies to molecular pathology and ADLTs ordered on hospital outpatients be made applicable to hospital inpatients in a consistent manner. It is administratively burdensome for both hospitals that collect the specimens and performing laboratories to have to track and bill specimens obtained from outpatients differently from those that are obtained from inpatients.

The current DOS exception for inpatient tests is based on orders occurring 14-days after discharge is a concern for inpatient molecular pathology. These order delays can result in a delay of care. The current inpatient exception is likely to lead to a delay in testing because it means the difference between the hospital paying the cost of expensive tests, versus the performing lab being able to bill separately. In these cases, patient care may be delayed just so that the clinician can order the test 14 days or more from the biopsy date so that the performing lab can bill for separate payment. We do not believe CMS's intent is to create an incentive that would delay patient care or set up differential practices where the cost of care is not transparent, because the cost of these tests should be clearly seen in the claims data. In conclusion, this order of 14 days after discharge criterion exists today could

result in delays in patient care when for many patients, each day of treatment delay during the diagnoses phase can detrimental. We encourage CMS to reconsider.

To be consistent between inpatients and outpatients, PRT recommends that the exception policy be that the clinician would certify, when ordering molecular pathology or ADLT tests, that the results of the test do not guide the treatment that is provided during the hospital inpatient or outpatient encounter. This certification could be attested to by the performing laboratory when it bills the tests with a modifier. Therefore, if the performing laboratory Date of Service overlaps with the dates of a hospital inpatient or outpatient encounter, CMS would read the applicable modifier, and would be able to make an exception when the test is a molecular pathology test, or ADLT, and pay the performing lab separately.

7. Quality and Value-based Purchasing Program Changes

The PRT appreciates the effort to align quality reporting programs to prevent duplication of measures among programs (Hospital VBP, Hospital readmission reduction, HAC Reduction, IPPS) and the attempt to create a parsimonious set of meaningful measures. We understand that specific quality-based measures will exist in one program – IQR, HVBP, HRRP or HAC Reduction thereby streamlining the reporting process while enhancing the usefulness and usability of the data.

The PRT supports the addition of a factor ("Factor 8") to consider a measure for removal from the Hospital IQR and other programs when "the costs associated with a measure outweigh the benefit of its continued use in the program". We understand that finalization of the proposal to add this factor has an impact on other segments of this IPPS Proposed Rule.

Below are the PRT comments on each of the programs.

Hospital Readmission Reduction Program:

The PRT supports the changes proposed for the claims-based readmission measures. The PRT supports CMS continuing to explore how best to account for social risk factors in the quality measures programs. Beneficiaries with social risk factors (i.e., income, education, lack of social support, lack of community resources) are at higher risk for noncompliance and poor outcomes. These patients require more intensive social services to achieve improved outcomes. Patient behavior has an impact on outcomes and the readmission rate.

Hospital Value Based Purchasing Program:

The PRT supports the changes proposed.

Hospital Acquired Condition Reduction Program

The PRT supports the changes proposed.

eCQM's

The PRT supports earlier removal of the eCQM measures. This would prevent the burden of maintaining the measures that are duplicative and will avoid expending additional resources and staff time on measures which are to be eliminated. PRT urges CMS to proceed with removal of the duplicative eCQM measures beginning with the 2019 reporting period to allow hospitals to focus on the remaining specific eCQMs contained in the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs.

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New Quality Measures Under Consideration

The PRT is concerned about the implementation of an across the board measure of mortality measure without fully understanding how clinical and socio-economic risk factors will be considered in establishing the patients' severity of illness. CMS states that they intend the measure will exclude "patients at the end of life and for whom survival is unlikely". How will this be identified? Even though CMS is considering exclusions such as patients enrolled in hospice, admitted primarily for metastatic cancer, those admitted with "specific diagnoses with limited chance of survival" and transfers from another inpatient facility, the PRT is concerned that providers who serve the most complex patient populations will be impacted disproportionally. We believe there are myriad other diagnoses that influence survival beyond the limited set of diagnoses listed in the proposal. In addition, CMS has listed as an exclusion as, "do not have a principal discharge diagnosis of "rehabilitation care: fitting of prostheses and adjustment devices"". Please note that with the implementation of ICD-10-CM, there is no longer a specific diagnosis code for "admission to rehab" and Official Coding Guidelines instruct coders, "When the purpose for the admission/encounter is rehabilitation, sequence first the code for the condition for which the service is being performed". An alternate method of excluding rehabilitation encounters will need to be considered. We agree that the calculated ratio of "observed" to "expected" is appropriate we would ask CMS to procedure with caution with the definition of how patients are risk adjusted to establish their severity of illness and risk of mortality.

Opioid-Related Adverse Events Electronic Clinical Quality Measure

While the PRT commends CMS on its leadership regarding the opioid epidemic, we have questions concerning this measure such as how is patient "harm" defined? CMS notes it intends to identify through query of the EHR, but we believe this will have to be an abstracted measure which CMS desires to avoid due to administrative burden. Furthermore, how will "chronic opioid users" be identified? We are also concerned with the lack of parity between DSM-5 and ICD-10-CM code definitions which could result in disparate data being reported which would impact the homogeneity of the data collected. We believe this measure requires more time to vet with stakeholders and to firm up answers to these questions.

Accounting for Social Risk Factors in Hospital IQR Program

The PRT notes that while dual eligibility may be one predictor of poor health outcome, we urge CMS to consider other social and economic indicators that contribute to a patients' outcomes.

Future Development and Adoption of eCQMs Generally

The PRT is concerned about CMS' proposal to share data with third parties that use machine learning and natural language processing. With the adoption of the EHR, one important goal has been the interoperability to facilitate sharing of information from different technology systems and software applications. While we believe that interoperability is an important goal for hospitals and providers, we do not believe these technologies have evolved where they are reliable and we are concerned with any conclusions that could be drawn from such technology from sharing health information with third parties.

Public Display of Data

The PRT continues to be concerned about the interpretation of data publicly displayed. We agree with CMS that the public display of data is of limited use because it cannot be easily interpreted by beneficiaries to influence their choice of providers. Furthermore, reporting the same measure in multiple programs makes the data even more confusing for beneficiaries.

Conclusion

The PRT appreciates the opportunity to provide comments on the FY 2019 IPPS Proposed Rule. We encourage CMS to continue to work with the provider community through the rulemaking process in order to create a stable and equitable payment system.

If you have any questions or comments on this letter, please contact Ms. Terri Rinker at 765-298-2110 or via email at: Terri.Rinker@ecommunity.com

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Updated April 2018