Provider Roundtable

August 17, 2018

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

Ascension Health
(AL, AZ, AR, CT, DC, FL, GA, ID, IL, IN, KS, KY, LA, MD, MI, MO, MN, MS, NY, OK, PA, TN, TX, WA, WI)

Baptist Health South Florida
(FL)

Carolinas HealthCare System
(NC, SC)

Community Hospital Anderson (IN)

Erlanger Medical Center
(TN)

Franciscan Missionaries of Our Lady Health System
(LA)

Hartford Hospital
(CT)

Kaiser Permanente, Southern California Permanente Medical Group
(CA)

University of Pittsburgh Medical Center
(PA)

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Re: CMS-1678-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 2018 Outpatient Prospective Payment System (OPPS) 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 the OPPS, 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 OPPS 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. Potential Revisions to Lab Date-of-Service Policy
2. Proposed Payment Rates Under the Medicare PFS for Non-excepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
3. 340B
4. Proposed Procedures That Would Be Paid Only as Inpatient Procedures
5. Request for Improvement & Changes
6. Packaging of Drug Administration Procedures
7. Quality
8. Fractional Flow Reserve (FFR)-CT
9. Evaluation of assignment of device-intensive procedures to C-APCs

1. Potential Revisions to Lab Date-of-Service Policy

CMS' proposals regarding the clinical laboratory date-of-service (DOS) policies impact both molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs). The PRT is grateful that CMS is addressing the issue of overly complex laboratory billing for both hospitals and performing laboratories, including situations in which hospitals themselves are the performing laboratory. Nonetheless, we have identified specific concerns with the agency's proposals and offer suggestions for consideration.

The PRT recommends that the future exception be applied to molecular pathology tests, any resulting pathology reflex testing, and ADLTs. These tests are important for guiding patient treatment plans, differ from regular laboratory tests, and are very technologically advanced. Because many hospitals currently lack the in-house technical expertise and/or infrastructure to perform molecular pathology tests, these tests are often sent out to a separate performing laboratory. Hence, in order to ensure that all hospitals can access these tests — including rural, community, academic, and specialty hospitals — the PRT encourages the future exception to apply to all molecular pathology tests and ADLTs.

The PRT requests that the proposed DOS exception apply to ADLTs and molecular pathology laboratory tests ordered for inpatients, outpatients, and non-patients or specimens. The inconsistencies in tracking and billing requirements for the same tests depending upon the type of account present significant administrative burdens. These burdens affect both hospitals that collect and/or receive these specimens as well as laboratories that process and bill for these specific tests, including when the hospital laboratory is the performing lab.

We note that consistency between inpatient and outpatient data is important for CMS' efforts to evaluate patient outcome data. Because inpatient claims do not include laboratory test HCPCS codes, CMS cannot use claims data to track outcomes for patients for whom these tests were performed. This hampers CMS' ability to evaluate how advanced testing contributes to cancer care, other advanced treatments, and the total cost of care. Two key pieces of information are needed to foster insights into patient survival and outcomes: accurate information on the tests' timing and HCPCS codes to identify the specific tests. In order for CMS to have access to this information on every beneficiary, the DOS exception policy must be consistent for hospital inpatients, outpatients and non-patients.

- The PRT recommends that future exception should apply to molecular pathology and ADLTs, as well as any reflex pathology services related to these tests.

- The PRT suggests that the future exception should apply to tests ordered on all patients – inpatients, outpatients and non-patients.
- The PRT believes that the laboratory performing the tests should be able to bill separately and receive separate Part B payment, whether it is an independent lab or a hospital-based lab.

In terms of the DOS of the molecular pathology or ADLT, CMS proposes:

1. The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department;
2. The specimen was collected from a hospital outpatient during an encounter (as both are defined 42 CFR 410.2);
3. It would be medically inappropriate to have collected the sample from the hospital outpatient other than during the hospital outpatient encounter;
4. The results of the test do not guide treatment provided during the hospital outpatient encounter;
5. The test was reasonable and medically necessary for the treatment of an illness.

Overall, the PRT agrees with CMS' proposal. We do have concerns about some of the requirements, however.

We believe the requirement that the physician order the test following the discharge date will be problematic when considering current clinician workflow in ordering laboratory tests. To help explain our concern and our suggested alternative, we present some background information below.

For molecular pathology and ADLT testing, the two specimen types obtained are blood and tissue. Clinicians order the ADLT or molecular pathology test either during an inpatient or outpatient stay when the specimen is collected, or prior to the stay if the available clinical information supports the need for the testing. These orders are not delayed until after the patient's discharge or after the specimen has been obtained. A clinician may order additional tests to be run on the specimen at the time of discharge, but that is not always the case. Many times, the patient must heal from surgery or the biopsy procedure before treatment can be provided. Often, all test results must be available in order for the practitioner to determine the best treatment plan; and, practitioners must frequently consult with others to ensure the best patient care. In all of these scenarios, testing results are not utilized for care while the patient is in the hospital; the testing's purpose is for treatment planning at a later date.

Current standard clinical and operational processes will make it very challenging to meet CMS' proposal that the order be made post-discharge; doing so would require a significant change in both clinician ordering and clinical practice. Postponing an order for testing until post-discharge does not align with current clinical workflows. It could also potentially delay care due to the "learning curve" required to change processes from occurring prior to and during encounters to occurring after discharge. We also note that the initial diagnosis may be made during an inpatient stay, and an order for biopsy and tissue testing made during the encounter.

Another concern is the requirement that the specimen must be collected during the hospital outpatient encounter. Hospitals may receive the tissue and/or blood samples from the physician's office or other location when the hospital itself is the testing laboratory. The orders come with the specimens, so it is impossible for the orders to be made "after discharge." While there is no inpatient or outpatient hospital encounter in this situation, CMS has not clarified that its policies extend to these tests — particularly when the current billing rule requires the hospital to bill the non-patient lab tests on hospital outpatient claims if the patient comes to the hospital on the same day due to an any reason unrelated to the molecular pathology or ADLT testing. CMS should allow facilities to continue billing

for these tests on a separate 014x bill type and should not require them to be included with any other outpatient hospital service.

The PRT supports the elimination of the current 14-day DOS exemption for three reasons. First, it delays laboratory orders, which can delay care. Second, hospitals (such as community and small facilities) that send the tests to outside laboratories to be performed must consider the timing of a delay, since it can determine whether the hospital pays for these tests or if the performing lab bills for them separately. Third, patient care may be delayed if a clinician orders a test 14 or more days from the biopsy date, which ensures the performing lab can bill for separate payment.

- The PRT supports the elimination of the 14-day DOS exemption.

Allowing separate billing for these services during an inpatient admission is similar to the process already utilized for vaccine administration; these services are billed on an individual UB in order to ensure that the benefit is applied appropriately. Adopting a similar process for molecular pathology and ADLT testing will enable clinicians to follow standard clinical workflows when ordering tests, remove the requirement that the orders be made post-discharge, allow appropriate payment to the performing laboratory, and ensure seamless treatment for patients.

Making this change will require an update to regulations at 42 CFR 411.15(m) concerning the requirement that "any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in §410.2 of this chapter) during an encounter (as defined in §410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients…is not covered."

- The PRT asks CMS to explicitly update regulations at 42 CFR 411.15(m) to allow separate coverage of molecular pathology and ADLT tests when billed separately from the hospital inpatient or outpatient encounter.

The PRT requests that CMS clarify that any laboratory billing for these specific classifications of tests may receive the appropriate separate payment. If a hospital laboratory has the infrastructure and expertise to perform these tests internally, it may perform and bill for the testing on a separate claim. For a hospital inpatient, the hospital would bill the tests on a Part B inpatient 012x claim (in the way that it currently bills vaccines provided during an inpatient stay, for example). For hospital outpatients where the blood draw or biopsy was made, the tests would be billed on a 013x claim; for referred specimens, tests would be billed on a 014x claim. Hospitals would still be allowed to refer specimens to a performing laboratory and pay the performing laboratory for the service if that is what the hospital and performing laboratory agree to do.

- The PRT requests that CMS clarify that any laboratory billing for these specific classifications of tests may receive the appropriate separate payment.
- CMS should allow molecular pathology and ADLTs from hospital inpatient and outpatient encounters to have separate billing based on test performance dates for all furnishing laboratories.

2. Proposed Payment Rates Under the Medicare PFS for Non-excepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

The PRT has provided detailed feedback, significant concerns, and recommendations in our comments on the CY 2018 Proposed Rule for the MPFS. We include a summary of our comment for informational purposes

We have fundamental concerns related to the additional payment reduction being proposed for CY 2018. In the last rulemaking cycle, CMS requested comments about the 50 percent reduction, which was an interim payment policy for CY 2017 for non-excepted off campus provider-based departments (PBD). We note that CMS never responded to the comments the agency received on this reduction, nor released any analysis of this issue.

CMS stated in the 2017 OPPS Final Rule:

> *"Therefore, in that proposed rule, we noted that we intended the payment proposal to be a temporary 1-year policy, applicable in CY 2017 only, while we continued to explore operational changes that would allow nonexcepted items and services to be billed by the off-campus PBD under the applicable payment system, which, in the majority of cases, would be the MPFS (81 FR 45687 through 45689)."*

Providers took CMS' intentions and statements on good faith, and believed the agency would not only consider the comments it received but also evaluate the applicable claims data before finalizing the reduction.

If this analysis has occurred and a conclusion has been drawn, the results have not been shared with the provider community. The PRT is extremely concerned that CMS proposes to take *an additional 25 percent reduction in payment*. We feel this is unconscionable.

We also are stunned that CMS issued this proposal in the same year that the agency is proposing a payment reduction for 340B drugs. If both proposals are finalized, the cumulative impact of these two proposals on hospitals would be devastating. The compounded effort involved in serving beneficiaries and low-income, dual-eligible patients is becoming a huge concern as facilities and physicians attempt to provide accessible and affordable services to beneficiaries and other needy patients in medically underserved areas.

The PRT feels very strongly that it would be egregious for CMS to advance this proposed payment reduction without further analysis and discussion. For this reason,

- The PRT strongly urges CMS to pause on *any* rate adjustments for at least two years after implementation of the -PN modifier. The agency currently lacks sufficient data to thoroughly evaluate the rate comparison from hospital off-campus PBD procedures and visits to office-based procedures and visits. Hospitals have not had any cost reduction in the off-campus site location PBD requirements related to the hospital's cost of operations, but continue to operate based on need and location of beneficiaries.
- The PRT urges CMS to base its future analysis on the top 25 reported codes, including *procedures* performed, given the data utilized under CMS' own methodology for CY 2017. For the CY 2017 payment, CMS generated the 50 percent adjustment after reviewing the top 25 codes reported with modifier –PO. We note that this data contained certain procedures that are typically performed in off-campus hospital based departments, such as urgent care centers, and are *not* typically performed in a physician office CMS' proposed additional reduction is based *solely* on comparing payment for HCPCS code G0463 to the difference between the

facility vs. non-facility payment for an E/M service under the MPFS. We fail to understand why CMS' analysis for CY 2017 included the top 25 codes— including both procedures and visits — yet, CMS' current proposal is based on *visit codes* only. The end result is that CMS has a flawed understanding of actual practice.

- The PRT urges CMS to conduct further data analysis on the proposal's procedural aspects. We believe that further data analysis is needed on the procedural aspect of this proposal. We also believe that a different payment adjudicator or default to the OPPS schedule would more accurately reimburse hospitals for procedures that are not performed in a physician office. We note the clear benefit to beneficiaries of being able to provide such procedures and services in the community.
- The PRT requests that CMS provide a technical clarification regarding the National Uniform Billing Committee (NUBC) requirement to report the locations address in form locator 1 of the UB-04 when a patient is seen/treated in multiple locations on the same date of service.

3. 340B

The PRT fundamentally and emphatically disagrees with CMS' proposal to reimburse for separately payable drugs obtained by Covered Entities via 340B purchasing at ASP *minus* 22.5 percent (ASP-22%). The proposal is of questionable legality and draws into question the boundaries of CMS' statutory authority.

As its rationale for this proposal, CMS states that "reports" indicate there has been no change to the charity care on hospital cost reports following the 340B program's implementation, and that hospitals availing themselves of discounted drug purchasing are not reinvesting these dollars into their communities. The PRT believes these statements are completely false and we strongly urge CMS to abandon this proposal. In the Proposed Rule, CMS notes that it lacks the data needed to understand where patients are being served and how resource savings are being utilized. The PRT recommends that CMS, in cooperation with the Health Resources and Services Administration (HRSA), evaluate where monies are being utilized to confirm that providers are redirecting 340B savings in an appropriate manner. It is extremely premature to suggest that reimbursing for 340B drugs at ASP-22% will further assist the underserved; CMS by its own admission doesn't understand where these monies are being utilized. We believe that CMS may not be seeing what it expects in the cost report as a result of timing: the 340B program's implementation and increased costs resulting from Medicaid expansion efforts could be masking CMS' expectations. Our own experience is that hospitals, including PRT member facilities, are absolutely providing and expanding services to our under-served and/or under-insured patients in our communities.

CMS states that it anticipates saving approximately $900 million as a result of this proposal — but acknowledges that this number could be "off." At the HOP Panel meeting in August, we heard the American Hospital Association (AHA) express concerns that CMS' estimate could be "off" by hundreds of millions of dollars. This concern aligns with the PRT's internal calculations, based on a sub-set of our member facilities, which suggest that we will experience a loss of *at least $100 million* in separately payable drug payments if this proposal is finalized. It is impossible that a handful of PRT member facilities could lose around $100 million if CMS accurately estimated the overall impact across all providers at only $900 million. We are deeply concerned that CMS' calculated savings estimate is understated to an extreme degree. The PRT is also concerned that CMS did not publish the details of its methodology in the Proposed Rule, which would have helped industry replicate the proposal's impact.

The PRT is very disturbed by CMS' assertion that this proposal may need to be "fixed later." Any incorrect calculation on the agency's part will have large, negative impacts on the Medicare program and adversely affect the health of beneficiaries who depend upon this program for their care. We also are puzzled about where the funds go if CMS' calculations are off by millions, or perhaps billions, of dollars. Are these dollars lost to the OPPS system altogether? If CMS discovers an error in the calculations, would the agency implement an adjustment in OPPS' future years (as it has had to do so often under the IPPS and, most recently, to OPPS due to the inaccurate calculations related to lab packaging)? We are unclear how CMS can, in good conscience, implement a program for which the agency cannot make accurate financial estimates. For this reason alone, although there are many more, we do not think CMS can even consider moving forward with its proposal.

- The PRT opposes CMS' proposal to reimburse for separately payable drugs obtained via 340B purchasing at ASP *minus* 22 percent. The PRT strongly recommends CMS to continue to pay for all separately payable drugs, for all OPPS hospitals, at ASP plus six percent (ASP+6%).

We also wish to raise operational considerations that CMS does not seem to have considered in its proposal. As CMS is aware, hospitals must meet many requirements before being approved by the Health Resources and Services Administration (HRSA) for participation in the 340B discount program. Once selected, however, hospitals still experience variability with respect to drug pricing under the 340B program. Many hospitals use a "virtual inventory system" for tracking 340B drugs. Hospitals must track, document, and achieve a certain number of "credits" in the system before they can access discount pricing vs. "regular" pricing. A facility can only receive 340B discount pricing *after* the credit requirement has been fulfilled. Discount availability is fluid and can change by individual drugs, by different manufacturers, and by time periods during the year. For this reason, a hospital's replenishment for stock of a specific drug at 340B pricing is dependent upon 340B pricing being available for that facility; if the pricing is not available, the hospital pays "regular" price for the replenishment.

Yet, CMS erroneously assumes that *all* hospitals that participate in the 340B program purchase *all* of their drugs under the discounted program. The drug supply system utilized for purchasing medications is completely separate from — and does not necessarily communicate with — the hospital's pharmacy drug dispensing system and the patient billing system. Because of the replenishment process already noted, it may be 3 to 10 days post-dispensing before the hospital knows whether a drug was replenished under 340B or at regular pricing. Even if a hospital wanted these systems to communicate more readily, the changes are cost-prohibitive due to expense and operational process changes, and cannot be done immediately because this process is controlled by vendor IT systems and changes to this extent are not made quickly.

A further concern with any OPPS payment reduction related to 340B is that the OPPS rate-setting process *already* accounts for 340B savings. Hospitals' cost reports already reflect the 340B acquisition based on expenses reported in the pharmacy cost center. These lower costs are already reflected in the drug cost-to-charge ratio (CCR), which will likely be lower since the cost to acquire these drugs is lower. The OPPS rate-setting process already reflects a blend of discounting/lower expenses with respect to 340B drug acquisition, in the annual application of CCRs to pharmacy charges. Hence, the PRT believes it is inappropriate for CMS to seek additional reductions without considering the program's existing impact on OPPS rates.

As confirmed during the 2017 HOPS Panel Meeting, CMS proposes that a modifier be appended to all drugs that are *not* purchased under the 340B program in order for them to receive full OPPS payment of ASP+6%. CMS also proposes that this same modifier be used by 340B hospitals to report their

separately payable drugs *not obtained* at a 340B discount. Both scenarios require significant administrative effort and operational burdens for hospitals. The burdens result from the fact that the modifier is applicable *only* to separately paid drugs; that non-340B hospitals will have to ensure changes are made on a quarterly basis; and that 340B hospitals will have to track, in real time, which drugs could be obtained with the 340B discount to report this on claims. While the first two are burdensome, the third activity is simply impossible for hospitals to do.

Additionally, requiring the modifier when drugs are purchased without the 340B discount is directly opposite to some state Medicaid program requirements that require the modifier to be reported when drugs *are obtained* under a discount. CMS' proposal would create additional operational burdens for facilities that serve dual-eligible beneficiaries. For example, for a single encounter where a 340B drug is provided, these providers will be required to submit a primary claim to Medicare without the modifier, and then rework the secondary claim for submission to Medicaid with the modifier when the drug was purchased at a discount. Rather than having the electronic communication from one payer to another (i.e. crossover), facilities will have to revert to prior processes in which secondary insurance were billed manually to ensure all services were reported correctly to both payers. And, when a beneficiary has tertiary insurance, which is quite common, a *third* claim must be created and submitted, since tertiary insurance does not require a modifier at all. **This is in direct opposition to the agency's stated desire to reduce providers' administration burden and strengthens our view that CMS should abandon its proposal.**

The PRT appreciates CMS' desire to address the needs of under-served and low-income patients. The proposed redistribution of funds in the OPPS does not, however, accomplish that goal and is outside the purview of CMS with this payment system. Frankly, it is completely egregious for CMS to consider robbing funds that are intended for covered entities, and to potentially redistribute those monies (including redistributing them to non-covered entities) through a budget neutrality mechanism. The proposed reductions in payments for drugs and redistribution of the savings across outpatient services within the OPPS conflicts with Congressional and HRSA's intent regarding 340B hospitals' use of cost savings to expand care for underserved patients.

Additionally, we understand that CMS seeks comments on what the agency should do with savings generated by implementing this proposal. As stated above, it is intensely problematic for CMS to redistribute the funds within OPPS (either by increasing the conversion factor for all providers or increasing the OPPS relative weights for other services). Doing so would take money away, in part, from the very hospital facilities it was intended to benefit. But, it is wildly inappropriate for CMS to even imply that the agency is considering taking any savings generated by this proposal *out of the OPPS* and either redirecting the monies to other Part B providers (i.e., physicians or ASCs) or putting them back into its own Trust Fund. If CMS finalizes this proposal (which we strongly oppose) it must keep any and all savings entirely within the OPPS payment system.

- The PRT urges CMS to retain any and all cost savings entirely within the OPPS, rather than redistributing them to fund a different payment system.

CMS also seeks public comment on whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured. The PRT must ask "why"? If the intent is to basically give it right back, then what is the point of the payment reduction? It is utterly nonsensical to force Covered Entities to "chase their own money."

The PRT resolutely opposes this proposal. We believe that CMS and providers will face numerous challenges in attempting to operationalize it. For example, CMS will face challenges if the modifier

used is not accepted for *all* drugs reported with a HCPCS code. Hospitals will have no choice but to consider removing the HCPCS detail from drugs that are unconditionally packaged, because it is too burdensome to have to continually adjust the modifier based on payment status. This action would, however, compromise the line item detail CMS receives via claims data. As the packaging threshold increases, and more and more expensive drugs are relegated to the "general drug expense" category, CMS will lose all details for trends and monitoring of specific drug utilization. As another example, we also note that both CMS and providers will face significant challenges if the modifier is applicable to facilities that do not participate in the 340B program. The fact that hospital participation in the 340B program varies over time will further complicate efforts to operationalize this proposal. These are just two examples of operational challenges that illustrate the problems with this program and the reason the PRT recommends against finalizing it.

CMS notes that it lacks the data needed to assess patient care and resource use under the 340B program. Many hospitals provide free housing for patients who need chemotherapy or radiation treatments or provide transportation services to bring patients to chemotherapy and physician appointments, so they do not have to travel during treatment days. Many hospitals provide meals to family members while patients are in the hospital. We encourage CMS and HRSA to evaluate where monies are being utilized to confirm that providers are redirecting 340B savings in an appropriate manner. This is a better investment of time than CMS' premature proposal to slash 340B drug reimbursement to ASP-22.5%. CMS and HRSA should have data analysis to support this proposal, as it will impact the population that the 340B program and other charitable actions are designed to help. We also suggest CMS conduct a retrospective reconciliation of specific medications, and the medications' quantity, purchased under the 340B program. This would ensure that the correct medications and correct quantities have been reconciled and reported to CMS.

- The PRT encourages HRSA to evaluate use of funds to ensure that providers are redirecting dollars in an appropriate manner for beneficiaries.

Finally, CMS expresses concern about beneficiary coinsurance in the Proposed Rule. The PRT does not believe this is a valid concern; nor should it be used to justify this proposal, since the majority of beneficiaries have secondary insurance that covers patient responsibilities.

4. Proposed Procedures That Would Be Paid Only as Inpatient Procedures

In the 2017 OPPS/ASC Proposed Rule, CMS solicited comments on the removal of total knee arthroplasty (TKA) from the Inpatient-Only (IPO) List. CMS reports that the agency received public comments that "were varied and nuanced" in response to its proposal. After reviewing the clinical characteristics and considering the comments, CMS proposes to move ahead and remove CPT code 27447 for TKA from the IPO List. In response to concerns about the potential for post-payment site-of-service reviews and denials by Recovery Audit Contractors (RACs), CMS proposes to prohibit RAC denial based on patient status for TKA procedures performed in the inpatient setting for a period of two years.

The PRT appreciates CMS' thoughtful consideration of the comments it received on this issue. We applaud CMS' reiteration that procedures that are not listed on the IPO List may be reimbursed either as inpatient or outpatient services. The PRT also supports the prohibition on RAC patient status reviews for TKA procedures for two years, as well.

Beyond these actions, however, the PRT recommends — as we have for many years — that the IPO List be eliminated. According to the CY2012 OPPS/ASC Final Rule, the IPO List specifies services

for which the hospital is paid only when the services are provided in the inpatient setting. This specification is intended to be based on the procedure's nature, the patient's underlying physical condition, and/or the need for at least 24 hours of post-operative recovery time or monitoring before the patient can be safely discharged.

The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the requirement that any procedure be reasonable and necessary. The PRT strongly feels that the appropriate level of care and site for delivering care should be determined based on the *physician's assessment of the individual patient's clinical state*. The physician is best-qualified to assess the specific patient's conditions and co-morbidities and to determine the appropriate setting for that unique patient. By requiring certain procedures to only be provided on an inpatient basis, CMS removes the physicians' opportunity to personalize patient care to the most appropriate setting (i.e., inpatient or outpatient).

Patient status is currently assigned based upon the physician's order for the individual patient. Decisions about patient status should be based upon the physician's clinical judgment, not the payment status. In fact, patient status is not necessarily tied directly to the procedure to be performed; rather, it depends upon the patient's clinical condition and the level of post-operative care required by that patient. Further, hospitals perform procedures in the operative suite that is best-equipped for that specific procedure, regardless of whether the patient is classified as inpatient or outpatient. And, the same resources are available to perform the procedure, regardless of the patient's status.

The IPO List presents an unnecessary administrative burden and financial impact for hospitals, with little impact on physicians. Hospitals are put in the position of requiring physicians to override his or her clinical judgment and make patient status determinations on the basis of payment rules. With other treatment scenarios, CMS allows physician judgment to overrule payment guideline. For example, under the 2-midnight rule, CMS allows exceptions to the benchmark to be determined on a case-by-case basis by the physician who is responsible for the beneficiary's care, subject to medical review.

The designation of certain procedures as Inpatient-Only provides numerous operational challenges to hospitals, as well. It requires hospitals to provide extensive education and official guidance to both medical staff and hospital schedulers, using the IPO list (Addendum E). The list, however, contains only the procedure CPT's short description. (For example, CPT 44960 is listed with a description of "Appendectomy." The code's long description is: "Appendectomy: for ruptured appendix with abscess or generalized peritonitis.") This lack of specificity can cause confusion on the part of both medical staff and hospital schedulers, who, without comparing the IPO list definition with the CPT's long description, may mistakenly schedule an inpatient admission for care that could safely be provided on an outpatient basis.

In a perfect world, physicians and schedulers would know in advance whether every scheduled procedure is on the IPO List or not. While hospitals have implemented processes in an effort to identify these procedures in advance, the reality is, not every IPO procedure is identified prior to surgery. The physician dictates the operative report for a procedure that, based on the physician's determination for the individual patient, was safely performed as an outpatient. When the record is coded (i.e., after the end of the episode of care and patient discharge), based on the operative documentation, it is determined that the procedure is on the IPO List. Because the procedure was performed as an outpatient, based on the physician's determination of the patient's individual clinical situation, it is too late at this point to explain to the physician that the procedure was actually on the IPO list and an inpatient order was required. Retroactive orders are not valid, so the hospital loses appropriate reimbursement for the procedure for a specific patient based on the IPO list.

For example, CPT 43281 describes hernia repair without mesh, and is not on the IPO List; CPT 43282 describes hernia repair *with* mesh. If a medically necessary change is made during the operative session (e.g. the physician determines that mesh is needed) the clinical professionals involved are unlikely to recognize that this change in procedure will have a downstream effect on the patient status and facility reimbursement. Typically, records are assigned CPT codes after the patient is discharged, based upon the operative report. In the scenario described, proper coding would lead to denial of payment for a medically necessary procedure at the level of patient care determined necessary by the physician, based upon the patient's clinical condition and the physician's medical judgment. Since CMS does not allow retroactive orders, the hospital will have no opportunity to receive payment for the medically necessary services provided.

CMS states in the Proposed Rule:

> *"The decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary."*

We understand, as stated, that physicians are able to receive payment. Nevertheless, our physicians experience significant frustration that hospitals have different rules for reporting services and receiving reimbursement. CMS' regulations regarding the 2-Midnight Rule already define an Inpatient stay. These same criteria should be applied to an Inpatient procedure. If the physician anticipates that the patient needs to stay over two midnights to ensure safe care and positive outcomes, then the patient should be admitted as an Inpatient. This would provide consistency for physicians who are trying to understand when CMS deems that a beneficiary should be admitted for an Inpatient level of care. It will also allow the physician to make a clinical determination, based on the individual beneficiary's situation, about whether Inpatient admission is required or not. It would remove the administrative burden for cases that change during the operative procedure. Finally, an unintended (but important) outcome of this change would be to reduce physician frustration about the different payment rules.

One of the PRT member's CMIO provides the following perspective:

> Physician reimbursement is not uniformly tied to hospital reimbursement and this can make it hard to engage physicians. The CMS guidelines on what is considered outpatient and inpatient procedures are not always consistent and do not always correlate with expected length of stay. For example, a laparoscopic appendectomy for acute appendicitis is outpatient, but a laparoscopic appendectomy for perforated appendicitis is inpatient. This designation is supposed to be made upon entry into the hospital, but may not be discovered until the patient is in the operating room. Further, it is not reasonable to expect the physician to recognize a distinction on this level of detail — he or she is busy providing sound medical care to a sick patient. It seems inconceivable that this coding language could be mastered by physicians. A patient's admission status is not relevant to the quality of care a patient receives and eats up valuable hospital resources that could be better focused on patient care.

- The PRT recommends that CMS eliminate the IPO List and any payment restrictions.
- The PRT urges CMS, if it maintains the IPO list, to allow exceptions when the physician determines them to be in the beneficiary's best interests, subject to medical review.
- The PRT recommends that, if the IPO List is maintained, it should include the CPT code's long descriptions.

If CMS maintains the IPO List, the PRT has recommendations for specific procedures that should be removed from the List:

- CPT 43282; Laparoscopy, surgical, repair of paraesophageal hernia with implantation of mesh; we note that CPT 43281 (Laparoscopy, surgical, repair of paraesophageal hernia without implantation of mesh) is already reimbursed as an outpatient procedure under the OPPS and the only difference between the two procedures is the mesh utilization.
- CPT 23472; Arthroplasty, glenohumeral joint: total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))
- CPT 23474; Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component

In CY 2012, CMS removed CPT code 43770 from the IPO List: *43770: Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components) (SI J1).*

The PRT recommends that the following similar procedures also be removed from the IPO list:

- CPT 43772: Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
- CPT 43773: Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
- CPT 43774: Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components

CMS provided guidance that Modifier CA intent was changed but the modifier description was not updated: haven't updated verbiage regarding to I/OCE, technical documents, HCPCS Manual, Claims Processing Manual.

- The PRT requests that CMS update the I/OCE, HCPCS Manual, Claims Processing Manual, and other technical documents with the revised Modifier CA description, which allows application to IPO codes when the patient expires or is transferred before being admitted as an inpatient.

5. Request for Improvement & Changes

The PRT has submitted a variety of comments to the House of Representatives' Ways and Means Committee, as part of the "Red Tape Reduction" Project. Below we summarize our recommendations for improvements and changes to the OPPS.

Hold Medicare Recovery Audit Contractors (RACs) Accountable

The Medicare RACs cause significant burden to hospitals with their constant request for records and subsequent denials for payment. Because RACs are incentivized by contingency payments, they do not have any "skin in the game" when it comes to denying a claim. In other words, when a denial is overturned on appeal, the RACs do not lose anything. Yet, hospitals are forced to expend a tremendous amount of resources on appealing denials, just to keep money they were initially paid. Hospitals are very confident in their appeals, as evidenced not only by the huge backlog at the ALJ level but also by CMS' multiple recent programs through which hospitals settle claims at the ALJ level for a reduced payment. There is significant evidence that accounts get overturned at the various levels of appeal. The

PRT believes that the RACs should be held accountable for accounts they deny that are later overturned at any level.

- The PRT recommends that RACs face a financial penalty when a denial is overturned at any level of appeal, which allows application to IPO codes when the patient expires or is transferred before being admitted as an inpatient.

Expand Medicare Coverage of Telehealth Services

Advancements in Telehealth have been extremely rapid, with many extraordinary outcomes, as evidenced by the designation of Stroke Centers and their rapid treatment of neurological events. Telehealth and the advancement in this type of technology has grown far beyond the need for face-to-face physician care in rural areas. As technology continues to advance, the potential application of Telehealth is limitless. Telehealth offers Medicare beneficiaries increased access to care, lower-cost options for disease management and treatment, and ideal monitoring processes to keep patients with chronic conditions out of the hospital. Currently, Medicare only covers Telehealth services under certain conditions, which are governed by locale. Urban areas are typically not covered under this benefit.

- The PRT urges CMS to consider expanding coverage for Telehealth services to a wider range of Medicare beneficiaries beyond rural areas.

Rescind the "JW Modifier" Requirement for Certain Drug Claims

Currently, providers are required to report the "JW modifier" on certain Part B drug claims for discarded drugs/biologicals in single-dose or single-use packaging; they are also required to document the amount of discarded drugs/biologicals. Compliance requires complex coordination and specialized information technology (IT) solutions. In addition, the requirement creates a patient safety concern because it requires providers to record both the amount of medication administered and the amount of medication discarded on both the patient's bill and chart. Including two different amounts for a single medication administration increases the risk of human error with respect to entering and reviewing the record during the course of treatment.

The PRT suggests that a better approach to addressing wastage would be for CMS to encourage drug companies to manufacture and supply smaller quantities for the U.S. market. We note that hospitals must purchase what is available and drug manufacturers make their products available in smaller packaging lots in the U.S., compared to other countries.

If CMS is not prepared to sunset the modifier, the PRT recommends that its application be made temporary. We also encourage CMS to provide an analysis of trends of modifier's use now that the agency has one year's worth of data.

- The PRT recommends eliminating the use of the "JW modifier" for drug waste on Hospital Part B outpatient claims.
- The PRT recommends that CMS encourage manufacturers to provide smaller packaging in the U.S.

Eliminate the Inpatient-Only List

The PRT recommends the elimination of the Inpatient-Only List (IPO), for the reasons described in more detail above. The IPO is burdensome for both physicians and hospitals. Physicians have been extensively trained to select the most appropriate site and level of care for patients based on the medical condition and expectation of two-midnights of hospital care, rather than on the type of procedure being performed (i.e., inpatient vs. outpatient). It is burdensome for hospitals because compliance requires the intensive use of resources to monitor coding of both scheduled surgical procedures and any additional, unplanned procedures that occur during a scheduled procedure. When the latter event occurs, and an IPO procedure is performed during outpatient procedures, the patient must be admitted as an inpatient so the hospital can receive payment for the care provided. This admission must occur whether or not inpatient of care is medically necessary for that patient.

Furthermore, the list of inpatient procedures uses CPT codes, while hospitals bill inpatient procedures using ICD-10-PCS codes. CMS does not publish a crosswalk between the two, which complicates facilities' ability to map from one to the other. Hospitals face additional burdens stemming from CMS contractor audits of one-day inpatient accounts when the account is correct under the current IPO policy. Finally, the IPO List unnecessarily increases Medicare expenses by forcing procedures to be conducted in the inpatient setting (which has higher payment rates than the outpatient setting) long after technology and medical advances have made them safe for the outpatient setting.

- The PRT urges CMS to eliminate the IP only procedure list and allow the decision on the type of care needed to remain with physicians based on knowledge about the specific patient.

End Requirement for Observation Carve-out Times

When counting and billing observation hours, CMS requires hospitals to remove (i.e., "carve out") any observation hours during which therapeutic services that require "active monitoring" are provided. Complying with this requirement creates operational and administrative burdens for providers in two ways. First, the definition of "active monitoring" is left up to individual hospitals to determine. This causes hospitals to interpret "active monitoring" differently among themselves. Second, compliance frequently requires facilities to use a manual process to remove observation hours with active monitoring. If a facility chooses to use an automated system to remove charges, the process is often difficult and costly, and necessitates manual auditing of claims to ensure the software is functioning correctly. Although most observation care is packaged, hospitals are required to conduct this work even though it does not impact payment.

Further, the requirement was created in order to prevent "double payment" of services when the Composite Extended Assessment and Management (EAM) APCs were in use. CMS eliminated the Composite EAM for CY2016, and now uses Comprehensive APCs (C-APC) for Observation Services. Hence, the manual provision and billing requirement that once applied to Composite EAMs has no further application or utility.

- The PRT strongly requests CMS remove the requirement that hospitals carve-out hours during observation that include active monitoring.

Eliminate 72-Hour Hospital Admission Requirement to be Admitted to a SNF

Currently, a patient must spend three days (i.e., 72 hours) as an inpatient in an acute care hospital before Medicare will pay for post-hospital extended care services. These post-hospital extended care services include those provided by a skilled nursing facility (SNF). Part B outpatient hospital services — such as observation hours and time in the Emergency Department (ED) — do not count towards this three-day requirement. Observation was created in order for physicians to be able to determine the appropriate level of care for a patient. Once a patient is in Observation, the PRT believes that the physician should have the authority to recommend a SNF at that time, if warranted. When a patient no longer needs acute care services, we believe the patient should be transferred to the lowest level of care that continues to meet the patient's needs. If an SNF bed is available that meets the patient's needs, the patient should be transferred to it, regardless of the length of time spent in the ED or Observation. We believe that the 72-hour rule be eliminated, and that Medicare should cover the cost of this stay.

- The PRT recommends eliminating the 72-hour rule.
- The PRT recommends that Medicare pay for an SNF bed that meets the patient's needs, regardless of how long the patient spent in the ED or under observation.

Eliminate the Second Important Message from Medicare

Currently, based on subregulatory requirements, hospitals are required to provide beneficiaries with a written explanation of their appeal rights, and to obtain the beneficiary's signature attesting to having received this explanation, at the time of his or her admission to the hospital. This process is called "Important Message notification." If this Important Message notification was provided more than two days before the patient's discharge from the hospital, CMS requires the facility to provide the beneficiary with a second Important Message notification (i.e., a follow-up notification). This second notification provides information that is identical to that contained in the initial notice. Presenting a beneficiary with the same information twice during one hospital stay often results in patients feeling both confused and overwhelmed by paperwork. This requirement also causes waste and redundancy for the hospital and staff, by consuming time and resources required to produce the duplicative paperwork. Any benefit in presenting a second message is seriously outweighed by the confusion to the patient and the waste incurred by the facility.

- The PRT urges CMS to eliminate the need for a second notice to be issued.

Revise the Use of Medically Unlikely Edits

PRT members often encounter administrative and operational difficulties associated with medically unlikely edits (MUE) that intersect with CMS' packaging initiatives. It is a relatively common circumstance for some MUE to be triggered during the billing process. Providers are particularly likely to remove units and charges from their claims for packaged services that have MUE limits, in order to avoid denials. Since there is no separate payment under OPPS for these type of services, there is no logic for hospitals to appeal the denial, since the appeal will not result in additional payment. As a result, providers cannot report accurate cost data to CMS, CMS is not obtaining the correct cost of care for Medicare beneficiaries, and the agency lacks data on MUEs that should potentially be adjusted.

The PRT understands and appreciates that CMS wants to ensure that claims correctly represent medically necessary services. In many cases, however, the services being provided are, in fact, **medically necessary** despite exceeding MUE limits. It occurs, for example, with some medications, because CMS caps allowable dose units at a patient weight of 110 kg, and many of today's

beneficiaries are overweight or obese and exceed this cap. As a result, we believe there should be an administratively simple way for providers to correctly submit these charges and units to CMS — especially for packaged services — so that the agency's rate-setting process for **medically necessary services** is not corrupted.

CMS approved modifier-GD ("Units of Service Exceeds Medically Unlikely Edit Value and Represents Reasonable and Necessary Services") and added it to the OCE in January 2008. It is not, however, listed as an appropriate modifier to be reported for an MUE in CMS' FAQ 2277, nor is modifier -GD listed as an appropriate modifier on MAC websites researched by the PRT.

The PRT recommends that CMS:

- Review the utility of MUE limits for all packaged services (status indicator "N") and exclude these unconditionally packaged codes from MUEs;
- Publish the allowable units if CMS determines that MUE limits are necessary for packaged services, in order to help providers know when an outlier is present and validate their claims prior to submission;
- Recognize the modifier -GD in the Integrated Outpatient Code Editor (IOCE), so providers can "attest" to the veracity of the units and charges upon initial submission of claims.

<u>Eliminate Proposed Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging, or Modify the Implementation Plans to Reduce Provider Burden</u>

The PRT has provided detailed feedback and recommendations in our comments on the CY 2018 Proposed Rule for the MPFS. We include a summary of our comment for informational purposes.

CMS has proposed regulations that would require furnishing providers to report Appropriate Use Criteria (AUC) for advanced diagnostic imaging. The proposed regulations require furnishing providers to enter HCPCS codes and modifiers on advanced diagnostic imaging service claims in order to receive payment. These HCPCS codes and modifiers would report what AUC were accessed, by which Clinical Decision Support Mechanism (CDSM), and whether the diagnostic test adhered to those criteria. This proposal presents a myriad of administrative burdens for furnishing providers (both physicians and hospitals), given that these facilities are not necessarily the ordering providers. These burdens include the need to obtain the required information from the ordering provider, translate the information into the appropriate codes, and develop a process for entering information onto claims. The proposed process also increases the risk of delaying patient care while the required information is being obtained from the ordering provider, and of hospitals billing for services that do not meet AUC. The PRT believes that the resources required to implement the AUC program would be better applied toward promoting Value-Based Purchasing and improving beneficiary care.

- The PRT strongly recommends that the mandatory use/implementation of AUC for advanced diagnostic imaging services be delayed to at least CY 2020, and that there be no payment impact to providers before CY 2020.
- The PRT encourages CMS to expand the voluntary reporting period through the end of CY 2019, begin its educational and operational testing period in CY 2019, and continue this educational/operational testing period through CY 2020.
- The PRT recommends that CMS provide instructions related to orders written prior to the effective dates (i.e., reporting and denial) of the requirement, when the service is provided after the implementation of the AUC reporting requirement's two phases.
- The PRT suggests that CMS define the required information an ordering professional must

include related to the AUC consultation on *every* referral to a furnishing provider for the applicable imaging services. This will facilitate entry of the information, assign responsibility for accurate determination of the HCPCS and modifier to the ordering provider, and insure the integrity of the claims data since the ordering provider has the responsibility of consulting the appropriate AUC.

- The PRT urges CMS to define "reasonable efforts" made by the furnishing provider to obtain AUC consultation information from the ordering provider. CMS should also specify steps that can be taken with respect to rendering the service after those reasonable efforts have been made.
- The PRT recommends that CMS use a G-code to identify circumstances where no AUC consultation could be reported, and establish a modifier to indicates the ordering provider did not report an AUC consultation to the furnishing provider.
- The PRT recommends that CMS define the proposed modifier to be used when an AUC consultation is not made due to the presence of an emergency medical condition (EMC) such that it includes a suspected EMC as well.
- The PRT encourages CMS to create some type of identifier for providers that have obtained a hardship exception and make public information about these providers, and their initiation and discontinuation dates for the exception.
- The PRT requests CMS to provide guidance about situations when the interpreting physician performs different or additional tests than those ordered, in accordance with the guidance in 100-02, Chapter 15, Sections 80.6.2 – 80.6.4.
- The PRT recommends that CMS clarify that a CDSM response indicating an ordered imaging service does not adhere to AUC criteria does not necessarily imply that the services were not medically necessary and reasonable.
- The PRT urges CMS to prohibit post-payment reviews based upon AUC criteria not being met for a specific imaging service.
- The PRT recommends that CMS exempt, from the AUC consultation requirement, claims for services that are determined, after an AUC-related service has been provided, to be ineligible for inpatient Part A coverage. This would include claims billed as inpatient Part B and claims that were improperly assigned inpatient status and later billed as outpatient, when an appropriate order is present.

<u>Require all Medicare Administrative Contractors (MACs) to Have Similar Payment Policies</u>

MACs have historically have had the latitude to make policies that they felt were appropriate for their geographic areas and patient populations. As CMS has become more standardized in its own policymaking, however, it no longer makes sense for MACs to have different procedure guidance. The PRT believes that, if a diagnosis code is covered under one MAC's Local Coverage Determination (LCD), it should be covered under *all* MACs' LCDs. The services and patient conditions are the same, and therefore the coverage requirements should be the same.

We believe it is not only confusing but also grossly unfair that a beneficiary has different level of coverage for the same procedure, merely because he or she crossed a state line into a different MAC. Consider a beneficiary for whom the closest hospital may be across a state line, who experiences coverage differences by entering a different MAC's territory. Several PRT members have hospital markets that are in different MAC areas.

Or, consider a beneficiary with cancer who spends the summer in Minnesota and the winters in Florida. This beneficiary risks not being able to get needed care if one or the other MAC has issued an

LCD. These patients have the same diagnosis in either state, and receive the same treatment in either state, but LCDs results in a coverage difference. One example is of inconsistent coding guidance is in how administration of Denosumab Prolia/Xygeva® is to be reported. Some MACs say to report it with 96372 (no-chemo, SubQ/IM), while others say to report it with 96401 (chemo SubQ/IM code). Providers must code different administration service for the same medication depending on the MAC's requirement.

- PRT recommends that, when a diagnosis code is covered under one MAC's Local Coverage Determination (LCD), it should be covered under *all* MACs' LCDs.
- The PRT requests that MAC Medical Directors meet on a regular basis to ensure consistent coverage regarding beneficiary services.

6. Packaging of Drug Administration Procedures

CMS is seeking comments on a new proposal to package low cost drug administration services; today, these services have a status indicator of "S" and are not subject to packaging or multiple procedure discounting. The only exception is when these services are present on a C-APC claim, in which case the PRT understands that the drug administration codes would be packaged under the single primary procedure C-APC. The PRT understands the concept and purpose of packaging under the OPPS, but disagrees that low-cost drug administration services are the same or similar to other low-cost "ancillary" type services; therefore, we do not agree with CMS' proposal to package these simply because they are low in cost.

In the CY 2015 OPPS Final Rule CMS noted:

> *"We are conditionally packaging certain ancillary services when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service. The initial set of services packaged under this ancillary service policy are the services assigned to APCs having an APC geometric mean cost (prior to application of status indicator Q1) of less than or equal to $100. This $100 geometric mean cost limit for the APC is part of the methodology of establishing an initial set of conditionally packaged ancillary service APCs, and is not meant to represent a threshold above which a given ancillary service will not be packaged, but as a basis for selecting an initial set of APCs that will likely be updated and expanded in future years."*
>
> *"In addition, we did not propose to package certain psychiatry and counseling-related services as we see similarities to a visit and, at the time of issuance of the CY 2015 OPPS/ASC proposed rule, did not consider them to be ancillary services. We also did not propose to package certain low cost drug administration services as we are examining various alternative payment policies for drug administration services, including the associated drug administration add-on codes."*

CMS admits that it utilized a $100 threshold as a guide for where to begin with ancillary service packaging, but states that the agency never intended to use this as a "real threshold." The PRT concurs that this threshold was an appropriate place to begin to identify services for *initial review*, and that additional packaging should be considered on the service's individual merits. But, we suggest that, if CMS utilizes any sort of threshold approach, it should always "exempt" services above that threshold from packaging (i.e., above $100). The agency does not currently do this. The PRT disagrees with the use of the $100 threshold without consideration of the fact that drug administration services are *fundamentally different* from other services.

We outline our many concerns with CMS' packaging proposal below.

The PRT believes it is unnecessary for CMS to introduce packaging of drug administration services, because existing coding policy per the National Correct Coding Initiative (NCCI) already takes care of bundling drug administration services when they are "integral, ancillary, supportive, dependent or adjunctive to a procedure." In other words, providers already know that there are instances when it is inappropriate to separately bill drug administration services with CPT/HCPCS code when billed with other services. As a result, there is no separate APC payment for those drug administrative services.

Chapter 11 of the 2017 NCCI Manual states:

> *"Under the OPPS drug administration services related to operative procedures are included in the associated procedural HCPCS/CPT codes. Examples of such drug administration services include, but are not limited to, anesthesia (local or other), hydration, and medications such as anxiolytics or antibiotics. Providers should not report CPT codes 96360-96377 for these services."*

The fact that drug administration services differ from other services is illustrated by the fact that CMS' NCCI contains procedure-to-procedure edits that dictate coding policy for these services. There are hundreds of code pairs that restrict separate reporting of drug administration services. In some instances, a modifier can be used to bypass the edit and indicate that the drug administration service was separate and distinct from the main procedure. There are several such edits, including "standards of medical practice" "mutually exclusive procedures" and "CPT manual or CMS coding instructions." Each edit type indicates that the code pairs have been reviewed for any inappropriate separate billing of drug administration services.

Therefore, based on the existing coding requirement, the PRT disagrees with CMS' proposal for additional packaging and non-separate payment for drug administrative services. We strongly urge CMS to continue recognizing that these services are unique and should generate separate payment, even when they are performed with Emergency Department (ED) or clinic visits.

Individual drug administration service(s) represents services that are specifically identifiable, including: assessing the patient; confirming that the order is appropriate for the patient and has no contraindications that would affect patient care; confirming that the drug administration service is not part of another procedure or service; and administering the drug. In addition, the reported drug administration service(s) includes the cost and payment for all drugs that are packaged. Packaging drugs and now proposing to package drug administration services is layering packaging upon packaging which we believe is grossly inappropriate and a second reason we disagree with CMS' proposal.

- The PRT urges CMS to continue making separate payment for drug administration services, including those performed with Emergency Department (ED) or clinic visits.

The PRT is also concerned that CMS' proposal would result in packaging upon packaging. Since non-pass through drugs that fall below the packaging threshold are packaged, conditionally packaging drug administration services would result in inappropriate packaging upon packaging.

We also note that the change in status indicator from "S" to "Q1" would result in individual services being packaged if the claim includes another "S," "T," or "V" service. It further means that only one unit of drug administration service would be paid, whereas today each unit is paid. This will significantly and inappropriately reduce payment in instances when a patient needs multiple SQ/IM injections and/or antigen therapy services.

The PRT has particularly strong concerns about the "packaging upon packaging" that will occur if CMS finalizes its proposal to package certain chemotherapy drug administration services since drugs are already being packaged. These services include:

- 96401 Chemo anti-neopl sq/im
- 96402 Chemo hormon antineopl sq/im
- 96405 Chemo intralesional up to 7
- 96549 Chemotherapy unspecified

Due to the CPT facility coding hierarchy and reporting requirements, if CMS finalizes this proposal, we believe that higher cost chemotherapy drug administration services could be packaged into lower-intensity drug administration services, such as hydration or other non-chemotherapy services. This risk is yet another reason why CMS should take more time to evaluate what sort of packaging, if any, might be appropriate for drug administration services.

- The PRT urges CMS not to implement this proposal due to the fact that it would result in inappropriate packaging upon packaging.

Third, the PRT disagrees with CMS' inclusion of vaccine administration services in its list of proposed drug administration codes to package, since this is a preventive service. A vaccine is a drug that is not "integral, ancillary, supportive, dependent, or adjunctive to a procedure" as described above. Rather, a vaccination is a unique service that is needed because the patient has a specific vulnerability and requires the ordered vaccine. Vaccines and vaccine administration are paid separately even when they are rendered to an inpatient during a Part A stay. Hospitals are instructed to bill on a separate 012x claim to receive separate payment precisely because vaccines are considered unique and individual services in their own right. They are, therefore, appropriate for separate payment and should not be subject to packaging under the OPPS.

- The PRT recommends that vaccine administration is appropriate for separate payment and should not be subject to packaging.

Fourth, the PRT opposes this proposal because the resulting increase in packaging will dilute the information available to CMS to ensure that packaged services are included in the rate-setting process. We believe that CMS must, given the exponential increase in conditionally packaged codes, make provisions to promote appropriate payment for, and future rate-setting use of, these services when they are performed and billed without a separately payable APC service.

Specifically, we note that CMS has not performed a comprehensive analysis of the impact of its packaging policies since the creation and implementation of C-APCs, and the agency's dramatic expansion of services that are packaged. The PRT requests that CMS analyze how both packaging and C-APCs are working *before* the agency proceeds with additional packaging proposals. We are starting to see larger and wider cost disparities in C-APCs, which is concerning. The PRT is also concerned by CMS current policy of capping payment at the APC family's highest APC. We are specifically concerned about what happens with costly combination of services that, based on the C-APC methodology <u>should</u> receive either a complexity adjustment or add-on payment, but are capped because they are already assigned to the highest APC in the family. No full analysis of the current impact of packaging policies has been conducted, although additional services continue to be packaged into the packaged services.

- The PRT strongly recommends that CMS conduct a comprehensive analysis of its packaging policies' impact before implementing more packaging proposals.

Despite our concerns, we encourage CMS to explore the creation of C-APCs for common drug administration encounters. The agency should evaluate whether drug administration encounters with separately identifiable clinic visit services (i.e., G0463-25) would qualify for complexity adjustments under existing thresholds for complexity adjustments. We also believe that new thresholds could be designed specifically for drug administration services that are frequent and/or common. We recommend that CMS investigate this option in conjunction with key stakeholders that specialize in oncology, since many drug administration services are related to cancer treatment.

We also strongly recommend that CMS evaluate trends in the payment-to-cost ratios for each OPPS provider over the last 6 years to determine if this ratio is remaining stable by hospital compared to the overall average, or if it is trending up or down for certain types of hospitals. Without this analysis, any additional packaging proposals (either conditional or unconditional) and new C-APCs could adversely impact the OPPS' averaging concept and severely impact certain types of hospitals. The PRT recommends that CMS delay any further packaging policies until the agency has completed a detailed impact analysis on individual hospital's payment-to-cost ratios.

We also urge the agency to release more comprehensive proposals for creating larger groups of drug administration services, as we understand that is the direction the agency would like to go. As CMS explores different ways to pay for drug administration services, we urge CMS to release its full methodology and data files so providers can review them in detail. The PRT asks that CMS publish its results and allow providers time to offer comments. Providers lack the resources to run the costly data analytics needed to provide CMS with alternatives but, if CMS releases its full methodology and data files, we could respond in a meaningful way.

- The PRT encourages CMS to explore the creation of C-APCs for common drug administration encounters.
- The PRT strongly urges CMS to evaluate trends in the payment-to-cost ratios for each OPPS provider over the last 6 years and analyze the stability or movement of this ratio compared to the overall average.
- The PRT recommends that CMS delay any further packaging policies until the agency has completed a detailed impact analysis on individual hospital's payment-to-cost ratios.
- The PRT recommends CMS release its data files and methodology related to the creation of C-APCs for drug administration services.

For the myriad of reasons noted above, the PRT urges CMS not to move forward with its packaging proposal regarding low-cost drug administration services. If the agency insists on doing so, we strongly object to packaging dollars associated with low-cost drug administration services into all other services. For example, if 95 percent of IM/SQ services represented by CPT 96372 occur specifically with revenue code 045x services, we urge CMS to keep the dollars incorporated into Emergency Department visits. We believe this will also apply to observation and other drug administration services, as well. Rather than CMS using its usual rate-setting methodology of spreading packaged dollars across the entire OPPS system — resulting in an increase of all APC relative weights commensurate with the packaging it finalizes — CMS should target the packaged dollars to be associated with where the expenses lie. It makes no sense for the APC payment for a radiology service to increase on the back of a decrease in drug administration services payment. We believe, however,

that it might be appropriate to raise payments for clinic visits, ED visits, observation services, and other drug administration services.

Finally, we wish to correct CMS' statement that an E/M visit cannot occur with drug administration services in a physician office setting. According to the NCCI manual, chapter 11, section B.8, drug administration services can be reported with E/M visits in both the facility and physician setting, so long as the visit is significant and separately identifiable. Modifier -25 is used in both settings to signify this situation. The only exception is that CPT code 99211 (which represents the lowest-level clinic visit in the physician office setting) cannot be reported with a drug administration service as the drug administration services have been valued to include this level — but all others can be. Therefore, we disagree with CMS' assertion that the variations in billing for different services in the physician and facility setting is a rationale for packaging low-cost drug administration services under OPPS.

In summary, providers have not had ample opportunity to present a thoughtful proposal regarding how to handle packaging for drug administration services. Providers are keenly aware that CMS' ultimate goal is to move to encounter-based payments, and that drug administration services will not be excluded from packaging indefinitely. We have not, however, had time to fully investigate and formulate a proposal to offer CMS. We have barely been able to scratch the surface of assessing the impact of CMS' proposals to decrease 340B payments and non-excepted off-campus provider-based departments. These two proposals alone have consumed almost all of the PRT's time. We urge CMS to release specific proposals far in advance so the provider community has sufficient time to evaluate them. We also encourage CMS to reinstate the Winter HOP Panel meeting so that stakeholders who are affected by CMS' proposals can present their concerns and suggestions to the Panel and to the agency.

- The PRT encourages CMS to release its proposals sufficiently in advance that the provider community can evaluate and provide comments upon them.
- The PRT suggests that CMS reinstate the Winter HOP Panel meeting, in order to increase stakeholders' ability to present concerns and suggestions to the agency.

7. Quality

The PRT congratulates CMS on its efforts to promote consistent delivery of higher-quality and more efficient health care for Medicare beneficiaries under the Hospital Outpatient Quality Reporting (OQR) program. We acknowledge and appreciate CMS' efforts to manage and alleviate the OQR's maintenance costs and administrative burdens by not introducing new measures for CY 2018 and by removing six existing measures for CY 2020 payment determination.

The PRT supports CMS' removal of *OP-21 (Median time to pain management for long bone fractures)*. With the growing epidemic of addiction and misuse of opioids across the country, it is important that these prescriptions be made judiciously and based on the most appropriate prescribing practices. OP-21 was based solely on the length of time to the initial administration rather than the pain management regimen across the continuum of care; hence, it risked leading to negative unintended consequences — including incentives to prescribe more opioids to meet quality standards and related measure within the HCAPHPS survey — that would create potential triggers for patients who are at risk of opioid addiction.

We also applaud CMS' recognition of the burden of manual chart abstraction *for OP-26 (Hospital OP volume data on selected OP surgical procedures)*. We also appreciate CMS' acknowledgement that this measure did not have an impact on clinical quality. This measure sought only to provide insight on

the number of surgical procedures, which is already monitored by facilities. We encourage CMS to also base any future quality measures under OQR on service outcomes, rather than service volume.

We appreciate that CMS acknowledges the administrative burden and/or limited evidence linking continuing monitoring of the following measures:

- *OP-1: Median time to fibrinolysis*
- *OP-4: Aspirin at arrival*
- *OP-20: Door to diagnostic evaluation by a qualified medical professional*
- *OP-25: Safe surgery checklist use*

We believe that these measures have provided positive impact to patient outcomes by improving provider practices. But, based on data presented by CMS, we believe there is limited evidence that they improve patient outcomes. We appreciate CMS' removal of these measures.

Risk Adjustment for Social Risk Factors

CMS seeks comments about whether the agency should account for social risk factors in the OQR Program. The PRT supports CMS continuing to explore how best to account for social risk factors in the OQR Program. Beneficiaries with social risk factors (i.e., income, education, lack of social support, lack of community resources) may be at higher risk for noncompliance and poor outcomes. These patients may require more intensive social services to achieved improved outcomes.

The PRT believes that the patient's socio-demographic status (SDS) has an impact on their care and outcomes. We note, however, that certain quality measures may *not* require risk adjusting as the measure is based on internal hospital processes (e.g., time-based measures) when compared to those that measure follow-up rates. When outcomes are based on patient compliance, however, we concur that socio-demographic factors may play a larger role. For this reason, we recommend that CMS consider factoring in the SDS in the measure calculation method, for measures where patient behavior has an impact on outcomes.

In addition, the PRT requests that CMS provide more transparency on the risk-adjustment methodology for this proposed measure. The Proposed Rule provides only vague references to demographics, cancer types, clinical comorbidities, and treatment exposures that impact the risk adjustment. We believe that the patient's stage of cancer and co-diagnoses significantly impact the timing and severity of the symptoms, as well as the timing of their treatment.

- The PRT recommends that CMS consider factoring in the SDS in the measure calculation method when patient compliance impacts their outcomes.
- The PRT requests that CMS provide more transparency on the risk-adjustment methodology for this proposed measure, such as for demographics, cancer types, clinical comorbidities, and treatment exposures that impact the risk adjustment.

Delay OAS CAHPS Survey Measures (OP 37a-e): Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare

The PRT understands the need for a standardized assessment of a patient's overall experience for surgeries or procedures performed within a hospital outpatient department.

CMS proposes that hospitals will be required to contract with a CMS-approved vendor to collect survey data and report to CMS on behalf of the hospital. The inpatient version of this measure (HCAHPS) uses a self-administered survey. The PRT seeks clarification from CMS about why the outpatient version of this (very similar) survey does not use same administration method.

The Hospital Value-Based Payment Program proposes to remove HCAHPS pain management dimension questions due to confusion about the questions' intent and public health concerns about the prescription opioid overdose epidemic. The PRT shares these public health concerns. We do not understand why the proposed outpatient version of the survey includes questions related to pain management. We understand that the question, "At any time after leaving the facility, did you have pain as a result of your procedure?" is a control question; yet, we are concerned that it leads to patient perceptions about their overall care that may, in turn, result in negative responses throughout the survey.

There are 37 questions on the proposed OAS CAHPS survey, while the HCAHPS contains only 21 items. The PRT questions the need for a longer survey on short hospital outpatient stays compared to inpatient stays.

The Measures Application Partnership (MAP) notes that these measures are also included within other programs. The PRT supports MAP's recommendation that CMS consider how these measures are related to other existing ambulatory surveys in order to ensure that patients and facilities are not overburdened by multiple surveys.

- The PRT requests that CMS carefully compare the proposed OAS CAHPS survey questions to the inpatient/HCAHPS version of the survey.
- The PRT recommends that CMS align the outpatient version of patient's experience of care survey with the current inpatient version from a content, timeline and administration method standpoint.
- The PRT encourages CMS to review these requirements to prevent duplication of effort on the part of providers and provide a uniform process for beneficiaries who will be completing the surveys.

Electronic Submission of Data

As noted in previous comments, the PRT agrees that EHRs' evolution and infrastructure increases the capacity for electronic reporting of measures and creates opportunities to replace the burdensome chart-abstraction method of data submission. The PRT supports the concept of using data collected from EHRs, but we continue to oppose CMS having *direct access* to a facility's EHR for data abstraction. We believe that specific data submission from the EHR could be developed in order to provide necessary information electronically without increasing hospital burden. We would support access within our facility system firewalls to data in the EHR only when it specifically addresses the quality measure.

We do not support the use of a direct portal for CMS to have open access to all data within a patient's electronic health record. We encourage the development of systems to enable hospitals to submit only specific data elements in an electronic format. We approve of the terms in the EHR incentive program that provides a foundation for hospitals to send — and for CMS to receive — quality measures through electronic submission.

We also note that a requirement to submit data electronically may be premature and there is little confidence that health care providers are prepared to do so with great accuracy. Within the short-term, EHRs' prevalence and capacity is expected to significantly improve; data integrity will enable electronic submission of quality measures data to CMS.

- The PRT urges CMS not to use a direct portal to have open access to all data within a patient's EHR.
- The PRT encourages CMS to promote the development of systems for hospitals to submit only specific data elements in an electronic format.

Public Display of Quality Measures

CMS proposes to publicly report *OP-18c (Median time from ED arrival to ED departure for discharged ED patients – Psych/Mental Health Patients).* We note that OP-18b is currently reported but excludes psychiatric and mental health patients, as well as transfer patients. This measure is intended as an ED throughput measure that assesses efficiency.

The PRT agrees that wait time reductions can improve quality of care. We also agree that the data required for public reporting is already collected, so the measure presents no additional burden for Report publicly to meet CMS' goal to *"address a behavioral health gap in the publicly reported Hospital OQR program"* providers. The proposed measure is strictly about a *placement issue* and does not indicate anything about the quality of care received. We note that lack of availability of mental health care providers, socio-demographic factors, and insurance coverage restrictions are likely to impact the patient's placement — and that none of these issues is under the hospital's control. Further, it takes time for hospitals to coordinate placement for patients, and that this placement is dependent on characteristics that do not reflect the quality of ED services provided (i.e. availability of services in the community, etc.).

Hourly Labor Cost for Burden Calculation

CMS previously estimated that hospitals pay $30 per hour for activities associated with abstracting and submitting clinical data. CMS now proposes that these activities *"can be accomplished by staff with a median hourly wage of $18.29 per hour."* To bolster this claim, CMS quotes U.S. Bureau of Labor and Statistics (BLS) findings that this is the median hourly wage for "Medical Records and Health Information Technicians" who are "responsible for processing and maintaining health information data." Hence, CMS believes it is reasonable to assume that these individuals would be tasked with abstracting clinical data.

The PRT does not support CMS' assertion. The agency's description of the skill set for "Medical Records and Health Information Technicians" is flawed, since it misrepresents the actual skill set required for hospital personnel who abstract quality data. In reality, a Medical Records and Health Information Technician's skill set includes straightforward activities, such as validating that all paper documents have been scanned into the EHR and that discharge summaries are present, etc. Conversely, abstracting quality measures is a much more labor-intensive and complicated process for which clinical expertise is required (e.g., social worker, registered nurse). Staff must be able to understand the quality measure's intent, ensure that the appropriate information for each quality measure has been captured, and confirm that the correct information was abstracted from the patient's record. CMS presents a gross understatement of the qualifications needed, and hourly wage expected, for this activity.

- The PRT urges CMS not to reduce the suggested hourly rate for activities associated with abstracting and submitting clinical data.

8. Proposed Treatment of New and Revised CY 2018 Category I and III CPT Codes That Will Be Effective January 1, 2018 / New Technology APCs

In the Proposed Rule, CMS assigns status indicator "N" to the following new Category III CPT® code, effective January 1, 2018: 0503T (Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model). This code has a placeholder HCPCS code "02X6T" in Addendum B. We note that coronary FFR is a major technological advancement for diagnosis and potential treatment pathways for Coronary Artery Disease (CAD).

We believe that CMS proposes to package this service based on the OPPS CY2008 Final Rule to policy-package "Image Processing Services" (CMS-1392-FC). In this Rule, CMS described these services as *"supportive dependent services to process and integrate diagnostic test data in the development of images."* The agency has expressed concerns that continued separate payment for these services might incentivize inefficient and/or more expensive delivery of care. CMS believes that packaging is one way to promote delivery of care that are medically necessary and conserve hospital resources.

Yet, FFR-CT is not a post-processing service, is not used to enhance other images, or support an independent service. This new technology is an independent diagnostic service that produces a distinct 3-D model with functional values to analyze coronary blood flow. FFR-CT effectively assesses blood flow through the coronary arteries. The use of FFR-CT can, in fact, eliminate the need for more expensive and/or invasive coronary angiography for CAD. One study has found that FFR-CT diagnostic results led to the cancellation of 60 percent of cardiac catheterization patients who were referred based upon clinical grounds. For this reason, the PRT opposes the proposed packaging for this procedure and believes it should be separately paid. Doing so would promote CMS' goal to encourage provision of the most appropriate and cost-efficient services.

We believe that FFR-CT meets CMS definitions of New Technology because it is reasonable and necessary, and because the technology represents a complete service that cannot be appropriately reported by a new HCPCS code that could be appropriately assigned to a clinical APC. Further, this service is one that could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.

One of the PRT member facilities implemented an FFR-CT program last year, as part of an effort to improve chest pain assessment and ensure that angiography patients are good candidates for the procedure. FFR-CT helps meet these goals because it can assess CAD more effectively than traditional coronary CT angiography. Approximately half of the patients referred to coronary angiography to evaluate suspected CAD are found not to have the condition. Hence, FFR-CT enables the provider to more accurately diagnose the patient, select the most appropriate course of treatment, minimize unnecessary procedures, enhance patient care, and reduce expenses. The PRT believes that FFR-CT will eventually become an important component of cardiovascular care.

- The PRT opposes packaging of FFR-CT into APC 5571, because the associated CPT codes do not describe this service, and because the services is separate, distinct, and not routinely clinically prescribed for all coronary CTA evaluations.
- The PRT encourages CMS to assign CPT 0503T to APC 1516 (New Technology, Lev16 $1401 - $1500, SI "S") and pay for it separately until the agency has sufficient claims data (i.e., two years of data) to directly assign it into the most clinically appropriate APC.

9. Evaluation of assignment of device-intensive procedures to C-APCs

The PRT requests that CMS extend the pass-through period for HCPCS C1822 – *Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system* – until December 31, 2018. CMS' policy has been to maintain items for pass through status up to 3 years to insure that adequate claims data has been obtained. Many providers have had contracting issues with payers to be able to obtain reimbursement for the procedure; while we understand that this is not CMS' concern, it does affect the number of providers who have been able to obtain and submit claims for this device. It is within CMS' purview to extend the pass-through status for an additional year to insure that adequate cost data and beneficiary access to this device are maximized.

In considering the request to extend the pass through status for HCPCS code C1822, the PRT recommends that CMS consider an additional level of review for device-dependent procedure assignment to C-APCs. CMS utilizes the 2 times rule to evaluate the resource utilization and clinical homogeneity for APCs to insure appropriate placement of procedures for reimbursement. The PRT recommends that a similar process should be utilized to evaluate the assignment of device intensive procedures to a C-APC. The percentage of the device cost that is packaged into a procedure many times overwhelms the cost of the procedure, thus affecting the reimbursement in that C-APC.

- The PRT recommends that CMS institute a review methodology, similar to the 2x rule, to insure that the device intensive procedures are grouped based on resource utilization, device cost and clinical homogeneity.

Conclusion

The PRT appreciates the opportunity to provide comments on the CY 2018 OPPS 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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