

Regulatory Advisory

July 28, 2016

Medicare Outpatient PPS and ASC Proposed Rule for CY 2017

AT A GLANCE

At Issue:

On July 6, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2017 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to updating OPPS and ASC payment weights and rates, the rule proposes to implement the site-neutral provisions of Section 603 of the Bipartisan Budget Act (BiBA) of 2015. The rule also includes proposals that would continue to shift the OPPS more definitively away from a per-service fee schedule to a prospective payment system with larger payment bundles and additional packaging policies. Additionally, the rule would change the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain questions required under the hospital value-based purchasing (VBP) program, offer flexibility in the Medicare Electronic Health Record (EHR) Incentive Program, and changes the organ transplant performance thresholds and policies for organ procurement organizations. Comments on the proposed rule are due by Sept. 6. The final rule will be released around Nov. 1 and will take effect Jan. 1, 2017.

Our Take:

The AHA is extremely dismayed by the short-sighted site-neutral policies in the proposed rule. Hospitals and health systems and more than half of the House and the Senate requested that CMS provide reasonable flexibility when implementing Section 603 in order to ensure that patients have continued access to hospital care. However, the agency is instead proposing that there would be no payment made directly to hospital outpatient departments subject to the site-neutral cuts in 2017. In addition, CMS would not continue current reimbursement to hospitals that need to relocate or rebuild their outpatient facilities in order to provide needed updates and ensure continued patient access to health care services. These proposals are unreasonable and do not reflect the reality of how hospitals strive to serve the needs of their communities. It appears that CMS is aiming to freeze the progress of hospital-based health care in its tracks. We will submit detailed comments to the agency urging them to revise these misguided policies so that hospitals can continue to provide the highest quality health care to their communities.

The AHA is pleased with CMS's proposal to suspend the HCAHPS survey pain-management questions in the VBP program scoring methodology while the agency field tests new questions. Further, the AHA is pleased that CMS proposes a 90-day EHR reporting period for 2016, additional flexibility in the reported measures and the reduced threshold for some Stage 3 requirements. However, we are disappointed that CMS proposes to retain several unrealistic Stage 3 requirements, such as the required use of application program interfaces.

What You Can Do:

- ✓ Learn more about the OPPS proposed rule provisions by viewing a recording of the July 19 AHA members-only webinar, "The CY 2017 OPPS/ASC Payment System Proposed Rule: What You Need to Know." To download the recording, visit <u>www.aha.org/oppswebinar</u>.
- ✓ Share this advisory with your chief financial officer, chief information officer, chief medical information officer and other members of senior management, billing and coding staff, nurse managers and key physician leaders.
- ✓ Model the impact of the APC changes on your expected CY 2017 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2016-2017 are available on the AHA's <u>OPPS webpage</u>. To access these, you must be logged on to the website.
- Consider submitting comments to CMS about the impact that the Section 603 site-neutral provisions in the proposed rule will have on your hospital or health system on or before the Sept. 6 deadline. Look for a model comment letter from the AHA in August that you can customize with details about your own particular situation.

Further Questions:

Please contact Roslyne Schulman, director of policy, at <u>rschulman@aha.org</u> for more information about the proposed rule.

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BACKGROUND

On July 6, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2017 outpatient prospective payment system (OPPS)/ambulatory surgical center (ASC) proposed rule. In addition to standard updates to the OPPS and ASC payment systems, the rule proposes to implement the site-neutral provisions of Section 603 of the Bipartisan Budget Act (BiBA) of 2015. The rule also includes proposals that would continue to shift the OPPS more definitively away from a per-service fee schedule to a prospective payment system with larger payment bundles, such as additional comprehensive ambulatory payment classifications (APCs) and additional packaging policies. Additionally, the rule would change the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey pain questions required under the hospital value-based purchasing (VBP) program, offer flexibility in the Medicare Electronic Health Record (EHR) Incentive Program, change the organ transplant performance thresholds, and change policies for organ procurement organizations.

Comments on the provisions of the proposed rule are due to CMS by Sept. 6. A final rule will be released around Nov. 1 and will take effect Jan. 1, 2017.

This Regulatory Advisory highlights many of the rule's proposals. In addition, the AHA offers members a more <u>detailed summary</u> prepared by Health Policy Alternatives, Inc.

PROPOSED CHANGES TO THE CY 2017 OPPS

OPPS Update and Linkage to Hospital Quality Data Reporting

<u>OPPS Update</u>. The CY 2016 OPPS conversion factor is \$73.725. To calculate the proposed conversion factor for CY 2017, the agency adjusted the 2016 conversion factor by the fee schedule increase factor and made further adjustments for various budget neutrality factors. The fee schedule increase factor equals the proposed hospital inpatient market-basket increase, which is proposed to be 2.8 percent, reduced by a productivity adjustment of 0.5 percentage points and an additional reduction of 0.75 percentage points, as required by the Affordable Care Act (ACA). Thus, CMS applies a fee schedule increase factor of 1.55 percent for the CY 2017 OPPS proposed rule. Hospitals that do not meet the Outpatient Quality Reporting program (OQR) reporting requirements are subject to a further reduction of 2.0 percentage points, resulting in a proposed fee schedule increase factor of -0.45 percent. The resulting proposed CY 2017 OPPS conversion factor is \$74.909.

CMS estimates that the fee schedule increase factor and all other policies in the proposed rule would result in the following per-case changes in payment:

| All Hospitals | 1.7% |
|-----------------|------|
| Urban Hospitals | 1.6% |
| Large Urban | 1.4% |
| Other Urban | 1.7% |
| Rural | 2.3% |
| Sole Community | 2.3% |
| Other Rural | 2.2% |

These payment adjustments, in addition to other proposed changes in the rule, are estimated to result in a net increase in OPPS payments of approximately \$671 million in CY 2017, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization and case-mix. Taking into account estimated changes in enrollment, utilization, and case-mix, the increase in OPPS expenditures for 2017 is estimated to be \$5.1 billion. However this figure does not include an estimated \$500 million in program savings resulting from the proposed implementation of the site-neutral payment provisions of Section 603 of the BiBA (discussed below).

Proposed Section 603 Site-neutral Policies

CMS proposes to implement Section 603 of the BiBA, which requires that, with the exception of dedicated emergency department (ED) items and services, items and services furnished in new off-campus provider-based departments (PBDs) (those that began billing under the OPPS on or after Nov. 2, 2015) will no longer be paid under the OPPS. Instead these services will be paid under other "applicable payment systems" under Medicare Part B beginning Jan. 1, 2017. CMS estimates that these changes would reduce OPPS spending by approximately \$500 million in 2017.

Broadly, CMS proposes to implement Section 603 by:

- Creating and defining the term "excepted items and services" to describe those items and services that are excluded, or "excepted," from the Section 603 site-neutral payment system policy and, therefore, would still paid under the OPPS.
- Defining "off-campus PBDs" and proposing the requirements that would allow certain off-campus PBDs to retain their "excepted" status, both in terms of the facility itself, as well as for the items and services it furnishes.
- Establishing new payment policies for "non-excepted" items and services.

The AHA is extremely dismayed by the short-sighted Section 603 site-neutral policies in the proposed rule. Specifically, the agency proposes that there would be no payment made directly to hospital outpatient departments subject to the site-neutral cuts in 2017. In addition, CMS would not continue current reimbursement to hospitals that need to relocate or rebuild their outpatient facilities in order to provide needed updates and ensure patient access. These proposals are unreasonable and do not reflect the reality of how hospitals strive to serve the needs of their communities. It appears that CMS is aiming to freeze

the progress of hospital-based health care in its tracks. We will submit detailed comments to the agency urging them to revise these misguided policies so that hospitals can continue to provide the highest quality health care to their communities.

<u>Excepted Items and Services</u>. CMS proposes that the following "excepted items and services" would continue to be paid under the OPPS on or after Jan. 1, 2017:

- Items and services furnished in a dedicated ED.
- Items and services furnished by an off-campus PBD that meets <u>all</u> of the following requirements:
 - The PBD furnished and submitted a bill for a covered outpatient department service under the OPPS before Nov. 2, 2015.
 - The items and services are furnished at the *same location* that the PBD was furnishing such services as of Nov. 1, 2015.
 - The items and services are in the same clinical family of services (described further below) as the services that the PBD furnished prior to Nov. 2, 2015.

Dedicated ED. Section 603 exempts items and services furnished in an ED from the definition of "applicable items and services", meaning that they would continue to be paid under the OPPS. In doing so, the law references an existing definition in the Medicare Emergency Medical Treatment and Labor Act (EMTALA) that defines an ED as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, which meets *at least one of* the following requirements:

- 1. It is licensed by the State in which it is located under applicable State law as an emergency room or ED;
- 2. It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- 3. During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

As such, CMS proposes that all items and services furnished in a dedicated ED, as defined above, whether or not they are emergency services, would continue to be paid under the OPPS.

On-campus Locations. Consistent with Section 603, CMS proposes that all oncampus departments of a provider and the items and services provided by such departments would be excepted from the site-neutral payment reductions. Thus, on-campus PBDs would continue to bill and be paid under the OPPS. In accordance with Section 603, CMS references an existing definition in the current provider-based regulations, which defines on-campus to mean "the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings *but are located within 250 yards of the main buildings*, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus."

Remote Locations of a Hospital¹. In accordance with Section 603, CMS also proposes to except from site-neutral payment all items and services furnished within 250 yards of a remote location of a hospital facility. CMS notes that hospitals should use surveys or reports or other appropriate documentation to ensure that their off-campus PBDs are within 250 yards (straight-line) from any point of a remote location for this purpose.

<u>Policies Regarding Changes to Excepted Off-campus PBDs</u>. As noted previously, Section 603 excepts from the site-neutral payment policy off-campus PBDs that were billing under the OPPS for covered outpatient department services prior to Nov. 2, 2015. CMS notes that it has received a variety of questions from providers about whether changes to an excepted off-campus PBD, such as an expansion of services, relocation or a change of ownership, would affect its excepted status.

In the proposed rule, CMS notes that it believes that Section 603 excepted only offcampus PBDs as they existed at the time that Section 603 was enacted, including only those items and services furnished and billed by such a PBD prior to that time. The agency explains that it used as a guide in designing its policies the existing regulatory definition of a department of a provider, which includes both the specific physical facility and the personnel and equipment needed to deliver the services at that facility. CMS further notes that its proposed policies are consistent with its belief that Section 603 "is intended to curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."

Relocation of Excepted Off-campus PBDs. CMS proposes that an excepted offcampus PBD, and the items and services that are furnished by such a department, must maintain the same physical address that was listed on the provider's hospital Medicare enrollment form as of Nov. 1, 2015 in order to maintain its excepted status and continue to be paid at the OPPS rates. An excepted off-campus PBD that changes its location would lose that status and be subject to the site-neutral payment policy. CMS notes that in the case of addresses with multiple units, such as a multi-office building, the unit number is considered part of the address. In other words, an excepted hospital PBD could not move into another unit in its building and remain excepted.

¹ Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity.

CMS requests feedback on whether it should develop a clearly defined, limited relocation exception process for extraordinary circumstances that are outside the control of the hospital. In describing these, it mentions instances when an excepted off-campus PBD may need to relocate, including, for example, to meet federal or state requirements, or due to a natural disaster. Beyond these, the agency also seeks input on whether it should consider exceptions for any other circumstances that are completely beyond the control of the hospital.

Service Expansion in an Excepted Off-campus PBD. CMS proposes that excepted offcampus PBDs would continue to be paid at OPPS rates only for those items and services furnished and billed prior to Nov. 2, 2015. **Consequently, the agency also proposes that any expansion of services beyond the clinical families of services that had been furnished prior to this date would be paid according to the siteneutral payment policy.** However, CMS notes that it is not limiting the volume of excepted items and services within an existing clinical family of services that an excepted off-campus PBD could furnish.

CMS proposes that service types be defined by the 19 clinical families of hospital outpatient services described in Table 1 below. As such, the agency proposes that if an excepted off-campus PBD furnished and billed for *any specific service* within a clinical family of services prior to Nov. 2, 2015, that entire clinical family of services would be excepted and be eligible to receive payment under the OPPS. Addendum B of the proposed rule (available on CMS's website) contains the specific Healthcare Common Procedure Coding System (HCPCS) codes that map to each clinical family of services.

| Clinical Families | APCs |
|----------------------------------|--|
| Advanced Imaging | 5523-25, 5571-73, 5593-4 |
| Airway Endoscopy | 5151-55 |
| Blood Product Exchange | 5241-44 |
| Cardiac/Pulmonary Rehabilitation | 5771, 5791 |
| Clinical Oncology | 5691-94 |
| Diagnostic tests | 5721-24, 5731-35, 5741-43 |
| Ear, Nose, Throat (ENT) | 5161-66 |
| General Surgery | 5051-55, 5061, 5071-73, 5091-94, 5361- 62 |
| Gastrointestinal (GI) | 5301-03, 5311-13, 5331, 5341 |
| Gynecology | 5411-16 |
| Minor Imaging | 5521-22, 5591-2 |
| Musculoskeletal Surgery | 5111-16, 5101-02 |
| Nervous System Procedures | 5431-32, 5441-43, 5461-64, 5471 |

TABLE 1. PROPOSED CLINICAL FAMILIES OF SERVICES

| Ophthalmology | 5481, 5491-95, 5501-04 |
|--------------------------------------|---|
| Pathology | 5671-74 |
| Radiation Oncology | 5611-13, 5621-27, 5661 |
| Urology | 5371-77 |
| Vascular/Endovascular/Cardiovascular | 5181-83, 5191-94, 5211-13, 5221-24, 5231-32 |
| Visits and Related Services | 5012, 5021-25, 5031-35, 5041, 5045, 5821-22, 5841 |

Changes of Ownership and Excepted Status. CMS proposes that if a hospital, in its entirety, has a change of ownership and the new owners accept the existing Medicare provider agreement from the prior owner, the hospital's off-campus PBDs may maintain their excepted status. If the provider agreement is terminated, all excepted off-campus PBDs and the excepted items and services furnished by such an off-campus PBD would no longer be excepted. Further, individual excepted off-campus PBDs would not be permitted to be transferred from one hospital to another and maintain their excepted status.

Payment for Services Furnished in Non-excepted, Off-campus PBDs. CMS states that, under Section 603, items and services furnished by non-excepted PBDs, and certain items and services furnished by excepted off-campus PBDs, are not covered outpatient department services under the OPPS. Instead, it requires that payment must be made for those applicable items and services under another "applicable payment system" if the requirements for such payment are otherwise met. However, the agency notes that the law does not reference or define a specific "applicable payment system" under which payment is to be made.

For CY 2017, CMS proposes that the Medicare physician fee schedule (PFS) would be the "applicable payment system" for the majority of non-excepted items and services furnished in an off-campus PBD. Physicians furnishing such services would bill on the professional claim (CMS 1500 Form) and be paid at the higher "non-facility" rate under the PFS for the services for which they are eligible to bill. There would be no payment made directly to the hospital by Medicare.

CMS states that, while it intends in the future to provide a mechanism for an off-campus PBD to bill and receive payment for furnishing non-excepted items and services, at this time, there is no straightforward way to do so before Jan. 1, 2017. The agency claims that, at a minimum, numerous complex systems changes would need to be made to allow an off-campus PBD to bill and be paid as another provider or supplier type.

CMS intends the above proposal to be a one-year transitional policy while it explores operational changes that would allow an off-campus PBD to bill Medicare directly for the services it provides under a Part B payment system other than the OPPS beginning in 2018. The agency believes that it will be necessary to establish a new provider/supplier type for non-excepted off-campus PBDs so that they could bill and be paid under the

PFS for non-excepted items and services using the professional claim. As described further below, the agency solicits public feedback on the changes that might need to be made to enrollment forms, claim forms, the hospital cost report, as well as any other operational changes that might need to be made in order to allow an off-campus PBD to bill for non-excepted items and services under a payment system other than the OPPS.

Optional Enrollment of a Non-excepted, Off-campus PBD as another Provider/Supplier Type. CMS notes that a hospital would have the option of enrolling the non-excepted off-campus PBD instead as a free-standing provider or supplier type (such as an ASC or physician group practice), and would then be permitted to bill for the non-excepted items and services it furnishes under that payment system. For instance, if an off-campus PBD were to enroll as a group practice, it would bill on the professional claim for all of its items and services and be paid under the PFS at the non-facility rate in accordance with laws and regulations that apply under the PFS.

Impact of Other Statutory and Regulatory Provisions. CMS recognizes that its proposal to pay under the PFS for all non-excepted items and services may result in hospitals establishing new business arrangements with the physicians or non-physician practitioners who bill under the PFS. As such, the agency is soliciting public input regarding the impact of other billing and claims submission rules, the fraud and abuse laws, and other statutory and regulatory provisions on its proposals. Specifically, it is interested in public feedback regarding the limitations of the reassignment of billing rights rules; the limitations of the anti-markup prohibition; the application of the physician self-referral provisions to any compensation arrangements that may arise; and the application of the Federal anti-kickback statute to arrangements between hospitals and the physicians and other non-physician practitioners who refer to them.

Status of Certain Services Not Payable under the OPPS. In addition, CMS describes options for some services that off-campus PBDs may furnish that are not billed or paid under the OPPS. These include:

- <u>Laboratory Tests</u>. Although laboratory tests are generally packaged under the OPPS, there are some circumstances in which hospitals are permitted to bill for certain laboratory tests and receive separate payment under the clinical laboratory fee schedule (CLFS).² CMS notes that, if a laboratory test furnished by a non-excepted off-campus PBD is eligible for separate payment under the CLFS, the hospital may continue to bill for it and receive payment under the CLFS. In addition, a bill may be submitted under the PFS by the physician (or hospital, for physicians who have reassigned their benefit to the hospital). CMS notes that, consistent with cost reporting requirements guidance and Medicare requirements, hospitals should report these laboratory services on a reimbursable cost center on the hospital cost report.
- <u>Partial Hospitalization Program (PHP) Services</u>. With respect to PHP services, the Social Security Act specifies that a PHP is a program furnished by a hospital,

² Laboratory payment policies under the OPPS are described further in another section of this advisory.

to its outpatients or by a community mental health center (CMHC). Because CMHCs also furnish PHP services and are ineligible to be provider-based, CMS notes that a non-excepted off-campus PBD would be eligible for PHP payment if the entity were to enroll and bill as a CMHC for payment under the OPPS. A hospital may choose to enroll a non-excepted, off-campus PBD as a CMHC, provided it meets all Medicare requirements and conditions of participation.

Comment Solicitation on Allowing Direct Billing and Payment for Non-excepted Items and Services in CY 2018. CMS seeks feedback regarding a new billing and payment policy proposal it intends to propose for CY 2018. Specifically, it seeks input on whether an off-campus PBD should be allowed to bill non-excepted items and services on the professional (not institutional) claim and receive payment under the PFS, provided the PBD meets all the applicable PFS requirements. Under this proposal, the agency intends that the PBD would still be considered to be part of the hospital and that the hospital as a whole would continue to be required to meet all applicable conditions of participations and regulations governing its provider-based status. But, for payment purposes, the off-campus PBD would be considered and paid (at the PFS rate) as a non-hospital setting, similar to a freestanding physician office or clinic. The agency is seeking public comments on whether there are administrative impediments for hospitals billing for such services or other considerations for allowing the hospital to do this, such as how the costs associated with furnishing such services might be reflected on the hospital cost report.

<u>Comment Solicitation for Data Collection</u>. **CMS seeks feedback on whether hospitals should be required to separately identify all individual excepted off-campus PBD locations, the date that each excepted off-campus PBD began billing and the clinical families of services that were provided by the excepted off-campus PBD prior to the Nov. 2, 2015 date of enactment of Section 603.** The agency notes that although the Medicare enrollment process requires that a hospital identify the name and address of each of its off-campus PBDs, such departments bill under the CMS Certification Number (CCN) of the hospital, rather than a separate identifier. Accordingly, at this time, the agency is unable to automate a process by which it could link a hospital's enrollment information to claims processing information to identify and link items and services furnished in a specific off-campus PBD. Therefore, the agency is seeking public comment on whether hospitals should be required to self-report this information to their Medicare Administrative Contractors.

Changes to the Inpatient-only List

<u>Procedures Proposed for Removal from the Inpatient-only List</u>. CMS uses its established methodology to identify six procedures (four spine procedure codes and two laryngoplasty codes) it proposes to remove from the inpatient-only list for CY 2017. These services include:

• CPT code 22840 (Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure));

- CPT code 22842 (Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22845 (Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure));
- CPT code 22858 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure));
- CPT code 31584 (Laryngoplasty; with open reduction of fracture); and
- CPT code 31587 (Laryngoplasty, cricoid split).

Solicitation of Public Comments on the Possible Removal of Total Knee Arthoplasty (TKA) Procedure from the Inpatient-only List. CMS is seeking public comments on whether it should remove TKA or total knee replacement, CPT code 27447 (Arthroplasty, knee, condyle and plateau, medical and lateral compartment with or without patella resurfacing), from the inpatient-only list. In 2013, CMS had made a similar proposal, but did not finalize it. The AHA and most other commenters opposed the 2013 proposal, claiming that it would be unsafe to perform outpatient TKA for Medicare beneficiaries. CMS notes that recent innovations, such as minimally invasive techniques, improved perioperative anesthesia, alternative post-operative pain management and expedited rehabilitation protocols, have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients.

CMS specifically asks for public comment on several questions, including how CMS could modify the Comprehensive Care for Joint Replacement (CJR) and the Bundled Payment for Care Improvements (BPCI) models if the TKA procedure were to be moved off the inpatient-only list. In particular, CMS is seeking comment on how to reflect the shift of some Medicare beneficiaries from an inpatient to an outpatient TKA procedure in the BPCI and CJR model pricing methodologies, including target price calculations and reconciliation process. For example, CMS would need to ensure target prices account for potentially higher risk profiles of Medicare beneficiaries who would continue to receive TKA procedures in inpatient settings.

Recalibration and Scaling of APC Relative Weights

CMS proposes to recalibrate the relative APC weights using hospital claims for services furnished during CY 2015. As in the previous year, CMS proposes to standardize all of the relative payment weights to the APC 5012 (Level 2 Examinations and Related Services) because clinic visits are among the most frequently provided OPPS services. That is, CMS proposes to calculate an "unscaled" – i.e., not adjusted for budget neutrality – relative payment weight by comparing the geometric mean cost of each APC to the geometric mean cost of the APC 5012.

To comply with budget-neutrality requirements, CMS proposes to compare the estimated unscaled relative payment weights in CY 2017 to the estimated total relative payment weights in CY 2016 using the service volume in the CY 2015 claims data. Based on this comparison, the proposed CY 2017 unscaled APC payment weights are

proposed to be adjusted by a weight scaler of 1.4059. The effect of the adjustment is to increase the unscaled relative weights by about 40.6 percent in order to ensure that the proposed CY 2017 relative payment weights are budget neutral.

Comprehensive APCs

<u>CY 2017 Proposed Comprehensive APCs (C-APCs)</u>. There are currently 35 C-APCs that package together an expanded number of related items and services contained on the same claim into a single payment for a comprehensive primary service under the OPPS.

For CY 2017, CMS proposes making a slight modification to its current C-APC payment policy methodology related to how it applies the complexity adjustment. Otherwise, CMS proposes to continue to include in a single payment all covered outpatient department services on a hospital outpatient claim reporting a primary service that assigned to status indicator "J1." Further, CMS proposes to continue to use status indicator "J2," as finalized in 2016, to designate C-APCs to which assignment is based on specific combinations of services performed together rather the presence of a single primary service identified by status indicator "J1." The only services on a claim that would be excluded from the C-APC payment are those that are not covered outpatient department services or that cannot, by law, be paid under the OPPS.

Using these proposed criteria, CMS proposes to add 27 new C-APCs in CY 2017, many of which are major surgery APCs within the various existing C-APC clinical families. The agency also proposes three new clinical families to accommodate new C-APCs, including nerve procedures; excision/biopsy/incision/drainage procedures; and airway endoscopy procedures. In addition, as discussed below, CMS proposes to develop a C-APC and dedicated cost center for bone marrow transplants.

All proposed C-APCs for 2017, including current C-APCs and those being proposed for 2017, are displayed in Table 2 below. Addendum J to the final rule contains data related to the C-APC payment policy methodology, including the list of proposed complexity adjustments. Please note that in the process of analyzing the proposed rule, the AHA uncovered several errors in CMS's discussion about the current and proposed C-APCs. Our summary above and the table below reflect the corrected information. However, as a result, this summary contains information that varies from that in CMS's preamble discussion and Table 2 below is not identical to CMS's table in the proposed rule.

TABLE 2. 2017 PROPOSED COMPREHENSIVE APCs

| C-APC | 2017 APC Title | Clinical Family ³ | Proposed New C-APC ⁴ |
|-------|--|---------------------------------|---------------------------------------|
| 5072 | | | * |
| 5073 | Level 3 Excision/ Biopsy/ Incision & Drainage | EBIDX | * |
| 5091 | Level 1 Breast/Lymphatic Surgery & Related Procedures | BREAS | * |
| 5092 | Level 2 Breast/Lymphatic Surgery & Related Procedures | BREAS | * |
| 5093 | Level 3 Breast/Lymphatic Surgery & Related Procedures | BREAS | |
| 5094 | Level 4 Breast/Lymphatic Surgery & Related Procedures | BREAS | * |
| 5112 | Level 2 Musculoskeletal Procedures | ORTHO | * |
| 5113 | Level 3 Musculoskeletal Procedures | ORTHO | |
| 5114 | Level 4 Musculoskeletal Procedures | ORTHO | |
| 5115 | Level 5 Musculoskeletal Procedures | ORTHO | |
| 5116 | Level 6 Musculoskeletal Procedures | ORTHO | * |
| 5153 | Level 3 Airway Endoscopy | AENDO | * |
| 5154 | Level 4 Airway Endoscopy | AENDO | * |
| 5155 | Level 5 Airway Endoscopy | AENDO | * |
| 5164 | Level 4 ENT Procedures | ENTXX | * |
| 5165 | Level 5 ENT Procedures | ENTXX | |
| 5166 | Cochlear Implant Procedure | COCHL | |
| 5191 | Level 1 Endovascular Procedures | VASCX | |
| 5192 | Level 2 Endovascular Procedures | VASCX | |
| 5193 | Level 3 Endovascular Procedures | VASCX | |
| 5194 | Level 4 Endovascular Procedures | VASCX | * |
| 5200 | Implantation Wireless PA Pressure Monitor | WPMXX | * |
| 5211 | Level 1 Electrophysiologic Procedures | EPHYS | |
| 5212 | Level 2 Electrophysiologic Procedures | EPHYS | |
| 5213 | Level 3 Electrophysiologic Procedures | EPHYS | |
| 5222 | Level 2 Pacemaker and Similar Procedures | AICDP | |
| 5223 | Level 3 Pacemaker and Similar Procedures | AICDP | |

³ **C-APC Clinical Family Descriptor Key:** AENDO = Airway Endoscopy, AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices, BREAS = Breast Surgery, COCHL = Cochlear Implant, EBIDX = Excision/ Biopsy/ Incision and Drainage, ENTXX = ENT Procedures, EPHYS = Cardiac Electrophysiology, EXEYE = Extraocular Ophthalmic Surgery, GIXXX = Gastrointestinal Procedures, GYNXX = Gynecologic Procedures, INEYE = Intraocular Surgery, LAPXX = Laparoscopic Procedures, NERVE = Nerve Procedures, NSTIM = Neurostimulators, ORTHO = Orthopedic Surgery, PUMPS = Implantable Drug Delivery Systems, RADTX = Radiation Oncology, SCTXX = Stem Cell Transplant, UROXX = Urologic Procedures, VASCX = Vascular Procedures, WPMXX = Wireless PA Pressure Monitor.

⁴ Asterisk (*) indicates proposed new C-APC for CY 2017.

| C-APC | 2017 APC Title | Clinical Family ³ AICDP | Proposed New C-APC ⁴ |
|-------|--|--|---------------------------------------|
| 5224 | | | |
| 5231 | Level 1 ICD and Similar Procedures | AICDP | |
| 5232 | Level 2 ICD and Similar Procedures | AICDP | |
| 5244 | Level 4 Blood Product Exchange and Related Services | SCTXX | * |
| 5302 | Level 2 Upper GI Procedures | GIXXX | * |
| 5303 | Level 3 Upper GI Procedures | GIXXX | * |
| 5313 | Level 3 Lower GI Procedures | GIXXX | * |
| 5331 | Complex GI Procedures | GIXXX | |
| 5341 | Abdominal/Peritoneal/Biliary and Related Procedures | GIXXX | * |
| 5361 | Level 1 Laparoscopy & Related Services | LAPXX | |
| 5362 | Level 2 Laparoscopy & Related Services | LAPXX | |
| 5373 | Level 3 Urology & Related Services | UROXX | * |
| 5374 | Level 4 Urology & Related Services | UROXX | * |
| 5375 | Level 5 Urology & Related Services | UROXX | |
| 5376 | Level 6 Urology & Related Services | UROXX | |
| 5377 | Level 7 Urology & Related Services | UROXX | |
| 5414 | Level 4 Gynecologic Procedures | GYNXX | * |
| 5415 | Level 5 Gynecologic Procedures | GYNXX | |
| 5416 | Level 6 Gynecologic Procedures | GYNXX | |
| 5431 | Level 1 Nerve Procedures | NERVE | * |
| 5432 | Level 2 Nerve Procedures | NERVE | * |
| 5462 | Level 2 Neurostimulator & Related Procedures | NSTIM | |
| 5463 | Level 3 Neurostimulator & Related Procedures | NSTIM | |
| 5464 | Level 4 Neurostimulator & Related Procedures | NSTIM | |
| 5471 | Implantation of Drug Infusion Device | PUMPS | |
| 5491 | Level 1 Intraocular Procedures | INEYE | * |
| 5492 | Level 2 Intraocular Procedures | INEYE | |
| 5493 | Level 3 Intraocular Procedures | INEYE | |
| 5494 | Level 4 Intraocular Procedures | INEYE | * |
| 5495 | Level 5 Intraocular Procedures | INEYE | |
| 5503 | Level 3 Extraocular, Repair, and Plastic Eye Procedures | EXEYE | * |
| 5504 | Level 4 Extraocular, Repair, and Plastic Eye Procedures | EXEYE | * |
| 5627 | Level 7 Radiation Therapy | RADTX | |
| 5881 | Ancillary Outpatient Services When Patient Dies | N/A | |
| 8011 | Comprehensive Observation Services | N/A | |

<u>Proposed Allogeneic Hematopoietic Stem Cell Transplantation C-APC</u>. Citing longstanding concerns raised by stakeholders regarding the accuracy of rate setting for allogeneic Hematopoietic Stem Cell Transplantation (HCST), CMS proposes to create a new C-APC 5244 (Level 4 Blood Product Exchange and Related Services). CPT code 38240 (hematopoietic progenitor cell; allogeneic transplantation per donor) would be assigned to this C-APC and a "J1" status indicator assigned to this code. The costs for all covered outpatient department services included on the claim, including donor acquisition services, would be packaged into the C-APC rate. The proposed 2017 payment rate for C-APC 5244 is \$15,267.

For future rate setting, CMS proposes to update the Medicare hospital cost report (CMS-2552-10) to include a new cost center (112.50) for "Allogeneic Stem Cell Acquisition." CMS notes that acquisition charges only apply to transplants for which stem cells are obtained from a donor; autologous transplants involve services to a beneficiary for which the hospital can bill and receive payment. In addition to the new cost center, CMS proposes to use the newly created revenue code 0815 (Allogeneic Stem Cell Acquisition Services) to identify hospital charges for stem cell acquisition for allogeneic bone marrow/stem cell transplants. In addition, for 2017 and subsequent years, CMS proposes to no longer use revenue code 0819 for the identification of stem cell acquisition charges for allogeneic bone marrow/stem cell transplants.

Proposed Changes to Packaging Policies

For CY 2017, CMS proposes several changes to its packaging policies.

<u>CY 2017 Laboratory Test Packaging Proposals</u>. In CY 2014, CMS established a policy to conditionally package the costs of clinical diagnostic laboratory tests in the OPPS. Specifically, CMS only pays separately for a laboratory test under the CLFS when: (1) it is the only service provided to a beneficiary on a claim; (2) it is an unrelated test, meaning it is on the same claim as other outpatient services, but is ordered for a different diagnosis and by a different practitioner than the other OPPS services (hospitals are instructed to use an "L1" modifier to indicate when laboratory tests meet this exception for separate payment); (3) it is a molecular pathology test; or (4) it is considered a preventive test.

For CY 2017, CMS proposes two changes to its laboratory packaging policy and requests public comment on each:

Discontinue the unrelated laboratory test exception (and the associated "L1" modifier that designates separate payment). With this proposed change, CMS would package all laboratory tests that appear on a claim with other outpatient department services. CMS believes that, in most cases, "unrelated" laboratory tests are not significantly different than most other packaged laboratory tests provided in the HOPD. The agency claims that some hospitals have reported that the "unrelated" laboratory test exception is not useful because they cannot determine when a laboratory test has been ordered by a different physician and for a different diagnosis than the other services reported on the same claim. CMS also believes that the "different physician, different diagnosis" criteria do not necessarily correlate with whether a laboratory test is related to other HOPD services.

 Expand the Molecular Pathology Exclusion to Include All Advanced Diagnostic Laboratory Tests (ADLTs). CMS believes that ADLTs,⁵ like molecular pathology tests, are relatively new and may have a different pattern of clinical use than more conventional laboratory tests. As a result, they may be less tied to a primary service in the outpatient department than other types of laboratory tests. CMS proposes to assign status indicator "A" (separate payment under the CLFS) to laboratory tests designated as ADLTs under the Clinical Laboratory Fee Schedule.

<u>Conditional Packaging Status Indicators "Q1" and "Q2</u>." To identify packaged payment versus separate payment of items and services, CMS uses status indicators applied to CPT and HCPCS codes. There are several different indicators for conditional packaging, which means that, under certain circumstances, items and services are packaged and, under other circumstances, they are paid separately.

Two of these status indicators indicate packaging of services furnished on the *same date*. Specifically, status indicator "Q1" packages items or services on the same date of service with services assigned status indicator "S" (Procedure or Service, Not Discounted When Multiple), "T" (Procedure or Service, Multiple Procedure Reduction Applies), or "V" (Clinic or ED Visit) and status indicator "Q2" packages items or services on the same date of service with services assigned status indicator "Q2" packages items or services on the same date of service with services assigned status indicator "C1" Other conditional packaging status indicators, such as "Q4" (Conditionally packaged laboratory tests) and "J1"/"J2" (Hospital Part B services paid through a comprehensive APC), package services on the *same claim*, regardless of the date of service.

For 2017, CMS proposes to change the logic for status indicators "Q1" and "Q2" so that packaging would occur at the claim level, instead of based on the date of service. CMS believes that this would align with other conditional packaging indicators and would ensure that items and services that are provided during a hospital stay that may span more than one day are appropriately packaged according to OPPS packaging policies. This proposed change would increase the conditional packaging of items and services because conditional packaging would occur whenever a conditionally packaged item or service is reported on the same claim as a primary service without regard to the date of service. CMS invites public comments on this proposal.

Wage Index

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. CMS has historically adopted the final fiscal year (FY) inpatient prospective payment system (IPPS) wage index as the CY wage index for adjusting OPPS payments. Thus, the wage index that applies to a particular hospital under IPPS also applies to that hospital under the OPPS. The agency proposes to continue this policy and use the final FY 2017 IPPS wage indices for calculating CY 2017 OPPS payments. For hospitals paid under the OPPS but not the IPPS, CMS proposes to continue its longstanding policy for CY 2017 to assign the wage index that would be

⁵ An ADLT is a test that is an analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result.

applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments. As in prior years, 60 percent of the APC payment will be adjusted by the wage index.

Outlier Payments

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. CMS again proposes to establish separate thresholds for CMHCs and hospitals. For CY 2017, CMS proposes to set the projected target for outlier payments at 1 percent of total OPPS payments – the same as in CY 2016 and previously. The agency proposes to allocate 0.01 percent of outlier payments to CMHCs for PHP services.

The rule continues to include both a fixed-dollar and a percentage outlier threshold. But, in CY 2017, CMS proposes to increase the fixed-dollar threshold for outliers to \$3,825, which is \$575 more than in CY 2016, to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2017, the cost of a hospital outpatient service would have to exceed 1.75 times the APC payment amount (the percentage threshold), *and* at least \$3,825 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare would make an outlier payment that is 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate.

Blood and Blood Products

For 2017, CMS proposes to continue to calculate the payment rates for blood and blood products using the blood-specific cost-to-charge ratio (CCR) methodology that it has used since 2005. CMS proposes to use the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center to set the proposed 2017 payment rates for blood and blood products.

CMS seeks comments regarding the adequacy and necessity of the current descriptors for the HCPCS P-codes describing blood products. For each of three main categories of blood products (red blood cells, platelets and plasma) the P-codes describe various treatments or preparations of the blood products, with each, in several cases, represented individually and in combination. CMS notes that in some cases hospital costs are similar for blood products with different code descriptors, and wants to know whether these P-code descriptors, with their associated granularity, best describe the state of the current technology for blood products that hospitals currently provide to hospital outpatients. The current set of active HCPCS P-codes that describe blood products also can be found in Addendum B to the proposed rule.

Proposed Device-intensive Procedures

For CY 2017, CMS proposes several changes to its policies regarding device-intensive procedures.

<u>Methodology for Assignment of Device-intensive Status</u>. Currently, device-intensive procedures are those procedures assigned to a device-intensive APC, which are APCs with a device offset greater than 40 percent. The device offset amount for an APC is the portion of the APC payment amount that is associated with the cost of devices used in procedures assigned to the APC. The device portion of a device-intensive procedure's payment is the same in both the hospital outpatient department and ASC setting. With the recent reorganization of the APCs to include a greater number of procedures, some APCs contain procedures that have high device costs but do not meet the 40 percent device-intensive threshold. Given this outcome, CMS proposes to change the device-intensive calculation methodology to calculate the device offset amount at the HCPCS code level rather than at the APC level so that device-intensive status is assigned to all device-intensive procedures that exceed the 40 percent threshold.

<u>Changes to Device Edit Policy</u>. For 2017, CMS proposes to apply its device claims editing policy on a procedure rather level rather than APC level, consistent with its proposal to make device-intensive determinations at the HCPCS code level. For 2017 and subsequent years, CMS would apply the device coding requirements to the newly defined (individual HCPCS code-level device offset greater than 40 percent) device-intensive procedures. Therefore, any device code, when reported on a claim with a device-intensive procedure, would satisfy the edit.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices. CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit using a value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. CMS specifies a list of costly devices to which this APC payment adjustment would apply.

For 2017, CMS proposes to identify the services to which the adjustment would apply using the newly defined set of device-intensive procedures. That is, the adjustment would apply to those procedures with an individual HCPCS level device offset greater than 40 percent, as described above.

<u>Proposed New Payment Policy for Low-volume, Device-intensive Procedures</u>. CMS proposes that the payment rate for any device-intensive procedure that is assigned to an APC with fewer than 100 total claims for all procedures in the APC would be based on the median cost, instead of the geometric mean cost. The agency believes that this approach will mitigate significant year-to-year payment rate fluctuations while preserving accurate claims-data-based payment rates for low-volume, device-intensive procedures.

Device Pass-through Applications

Device pass-through payments are intended to enable access to certain new medical devices. For CY 2016, CMS made changes to the OPPS device pass-through payment application process to improve transparency and stakeholder input. Specifically, in CY 2016, CMS adopted a policy to continue to accept and review device pass-through applications on a quarterly basis but to also include discussions of the preliminary pass-through applications in the next applicable OPPS proposed rule. For CY 2017, CMS

includes a discussion of three applications for which preliminary approval has not been granted based upon quarterly review. The three technologies are: (1) BioBag® (Larval Debridement Therapy in a Contained Dressing); (2) EncoreTM Suspension System; and (3) Endophys Pressure Sensing System or Endophys Pressure Sensing Kit. The agency invites public comment on whether the three technologies in question meet the newness, cost and substantial clinical improvement criteria.

Changes to Payment for Film X-Ray

CMS proposes to implement a non-budget neutral provision of the Consolidated Appropriations Act of 2016, which reduces OPPS payment by 20 percent for imaging services that are X-rays taken using film (including the X-ray component of a packaged service) furnished during 2017 and subsequent years. CMS would establish a new modifier that hospitals would be required to use on claims for these imaging services beginning in CY 2017. The HCPCS codes describing these imaging services to which this policy would apply can be found in Addendum B to the proposed rule, which is available on the CMS website.

The act also reduces payment for imaging services that are X-rays using computed radiography (including the X-ray component of a packaged service). Such imaging services furnished in 2018 through 2022 would receive a reduction of 7 percent in payment and in 2023 and subsequent years a 10 percent reduction.

CMS will propose a modifier to be used for these claims in future rulemaking.

Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access of Medicare Act (PAMA) of 2014 directs CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. Ordering practitioners will be required to consult AUC at the time of ordering advanced diagnostic imaging, and imaging suppliers will be required to report information related to such consultations on claims, for all applicable advanced diagnostic imaging services paid under the PFS, OPPS and ASC payment system.

The program's criteria and requirements are established and updated through PFS rulemaking and CMS addressed the initial component of the AUC program in the 2016 PFS final rule. The 2017 PFS proposed rule includes proposed requirements and processes for the second component of the Medicare AUC program: the specification of qualified clinical decision support mechanisms (CDSMs) under the program. The CDSM is the electronic tool through which the ordering practitioner consults AUC. The 2017 PFS proposed rule also proposes specific clinical priority areas and exceptions to the AUC consultation and reporting requirements. Please see our <u>advisory</u> on the 2017 PFS proposed rule for further details.

Payment Changes for Drugs, Biologicals & Radiopharmaceuticals

<u>Changes to Transitional Pass-through Period for All Pass-through Drugs, Biologicals</u> <u>and Radiopharmaceuticals</u>. By law, transitional pass-through payments for drugs, biologicals and radiopharmaceuticals (hereafter referred to as "drugs") are made for a period of at least two years, but not more than three years, beginning on the first date on which pass-through payment was made for the product. CMS accepts pass-through applications and begins pass-through payments for new pass-through drugs on a quarterly basis. Pass-through status, however, currently expires on a calendar-year basis, through notice-and-comment rulemaking, when at least two years of passthrough payments have been made, regardless of the quarter in which it was initially approved. Thus, the duration of the pass-through eligibility for a particular drug depends on the quarter of initial eligibility for pass-through payment.

Therefore, CMS proposes, beginning with pass-through drugs newly approved in CY 2017 and subsequent CYs, to allow for a quarterly expiration of pass-through payment status to afford a pass-through period that is as close to a full three years as possible for all pass-through payment drugs.

Packaging Policy for "Threshold-Packaged" and "Policy-Packaged" Drugs, Biologicals and Radiopharmaceuticals. The proposed payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status are based on fourth quarter of 2015 average sales price (ASP) data. Updates to the ASP-based rates will be published quarterly and posted on CMS's website through CY 2017.

CMS pays for drugs, biologicals and radiopharmaceuticals that do not have passthrough status in one of two ways: packaged payment or separate payment (individual APCs).

For CY 2016, CMS proposes to increase the packaging threshold for "thresholdpackaged" drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals, at \$110 per day, \$10 more than in CY 2016. Therefore, drugs costing less than \$110 would have their cost packaged in the procedure with which they are billed, such as a drug administration procedure. Drugs costing more than \$110 would be paid separately through their own APC.

There are exceptions to this threshold-based packaging policy for certain "policypackaged" drugs, biologicals and radiopharmaceuticals. Consistent with current CMS packaging policy, the agency proposes to continue to package the costs of all diagnostic radiopharmaceuticals; contrast agents; anesthesia drugs; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure (e.g., skin substitutes), regardless of whether they meet the \$110 per day threshold. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to this proposed rule (which is available on the CMS website).

Payment for Drugs and Biologicals without Pass-through Status that are not Packaged. For CY 2017, CMS proposes to continue its current policy and pay for separately payable drugs and biological at the "statutory default rate" of ASP plus 6 percent. CMS proposes that this payment requires no further adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals. <u>Proposed Payment for Biosimilar Biological Products</u>. The ACA authorized an abbreviated pathway for the licensing of biosimilar biological products. For 2017, CMS proposes to continue the policies it finalized in 2016. That is, it proposes to extend pass-through payment eligibility to biosimilar biological products and to establish pass-through payment using the same methodology applied to other pass-through drugs and biologicals. In addition, as it finalized in 2016, the agency proposes to pay for non-pass-through biosimilar biological products in the same way that other drugs and biological products are paid, using the ASP plus 6 percent payment methodology, subject to the threshold-packaging policy. Finally, CMS proposes that HCPCS coding and modifiers for biosimilar biological products would be based on policy established under the 2016 PFS rule.

New Technology APCs

CMS assigns new technology services that are ineligible for transitional pass-through payments and for which the agency has insufficient clinical information and cost data for appropriate assignment to a clinical APC group, to new technology APCs. These new technology APCs are designated by cost bands, which allow CMS to provide appropriate and consistent payment for designated new procedures that are not yet reflected in the claims data. An assignment to a new technology APC is temporary; the service is retained within a new technology APC until CMS acquires sufficient data to assign it to a clinically appropriate APC group. Currently, there are 48 levels of new technology APC groups with two parallel status indicators; one set with the status indicator of "S" and the other set with the status indicator of "T." These APCs have the same payment levels, but one set is subject to the multiple procedure payment reduction (T) and the other set not subject to the multiple procedure payment reduction (S).

CMS proposes to expand the new technology APC groups by adding three more levels with two parallel status indicators, Levels 49 through 51. These new levels range from the cost band assigned to proposed APC 1901 (New Technology – Level 49 (\$100,001 - \$120,000)) through the highest cost band assigned to proposed APC 1906 (New Technology – Level 51 (\$140,001 - \$160,000)). CMS proposes this expansion to accommodate the assignment of the retinal prosthesis implantation procedure to another new technology APC. The proposed payment rates for these New Technology APCs are included in Addendum A to the proposed rule. Table 10 in the proposed rule includes the complete list of the proposed additional six new technology APC groups for CY 2017.

Transitional Pass-through Payments

Congress created temporary additional, or "transitional pass-through payments," for certain innovative medical devices, drugs and biologicals to ensure that Medicare beneficiaries have access to new technologies in outpatient care. For CY 2017, CMS projects that pass-through payments will be 0.24 percent of total OPPS payments, or \$148.3 million. This includes \$112.7 million in pass-through payments for devices and \$35.6 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

Rural Adjustment for Sole-community Hospitals

CMS proposes to continue increasing payments to rural sole-community hospitals, including essential access community hospitals, by 7.1 percent for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy and items paid at charges reduced to costs. The adjustment is budget neutral to the OPPS and applied before calculating outliers and coinsurance.

Cancer Hospital Adjustment

CMS proposes to continue its cancer hospital update policy finalized in the CY 2012 OPPS final rule. Using the most recently submitted or settled cost report data, this policy would increase *each* of the 11 "exempt" cancer hospitals' OPPS payments by the percentage difference between its individual payment-to-cost ratio (PCR) and the weighted average PCR of the other hospitals paid under the OPPS (0.92). The adjustment is made at cost report settlement and is budget neutral.

Partial Hospitalization Program Payment

CMS currently uses four separate APCs to pay for PHP services, including two APCs for services furnished in hospital-based PHPs and two APCs for services furnished in a CMHC. For each setting there is currently an APC that describes the payment for a PHP day with three services and a separate APC that describes the payment for a PHP day with four or more services. Payments for hospital-based PHP services are calculated using only hospital data, and payment for CMHC PHP services are calculated using only CMHC claims data.

For 2017, CMS proposes to continue to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type. However, CMS proposes to replace the existing two-tiered APC structure for PHPs with a single APC by provider type for providing three or more services per day. CMS believes that these proposed changes would provide more predictable PHP per diems, particularly given the small number of CMHCs, and would generate more appropriate payments for these services by avoiding the cost inversions that hospital-based PHPs experienced in the CY 2016 OPPS/ASC final rule with comment period.

The resulting proposed PHP geometric mean per diem costs for CY 2017 are in Table 3 below.

TABLE 3. PROPOSED CY 2017 PHP GEOMETRIC MEAN PER DIEM COSTS

| Proposed CY 2017 APCs* | Group Title | Proposed PHP APC Geometric Mean Per Diem Cost |
|------------------------------|--|---|
| APC 5853 | Partial Hospitalization (3 or more services per day) for CMHCs | \$135.30 |
| APC 5863 | Partial Hospitalization (3 or more services per day) for hospital-based PHPs | \$192.57 |

* Note: APC 5853 would replace existing CMHC APCs 5851 and 5852. APC 5863 would replace existing hospital-based PHP APCs 5861 and 5862.

Beneficiary Coinsurance

CMS proposes to decrease beneficiary liability for coinsurance for outpatient services. As required by law, CMS maintains last year's maximum beneficiary coinsurance rate of 40 percent of the total payment to the hospital for that service. Under Medicare law, the cap on coinsurance rates is to be reduced gradually until all services have a coinsurance rate of 20 percent of the total payment.

Hospital Outpatient Quality Reporting (OQR) Program

The Tax Relief and Health Care Act of 2006 required CMS to establish a program under which hospitals must report data on the quality of outpatient care in order to receive the full annual update to the OPPS payment rate. Hospitals failing to report the data incur a reduction in their annual payment update factor of 2.0 percentage points.

CMS proposes a total of seven new measures for the CY 2020 OQR program – hospital admissions and ED visits for outpatient chemotherapy patients, hospital visits following outpatient surgery, and five measures derived from a new Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey. Detailed specification for the two hospital visit measures can be found on CMS's <u>website</u>, while details on the OAS CAHPS are available <u>here</u>. A list of finalized and proposed OQR measures can be found in Appendix A of this advisory.

The AHA is concerned that only one of the seven proposed measures has been endorsed by the National Quality Forum (NQF), providing little insight into whether the measures are accurate and fair representations of hospital performance. Furthermore, we believe CMS should assess all seven proposed measures for the impact of sociodemographic factors on performance, and incorporate adjustments where needed. Admissions and ED Visits for Chemotherapy Patients (OP-35). For the CY 2020 OQR program, CMS proposes OP-35, which calculates the rates of inpatient admissions and ED visits within 30 days for patients receiving chemotherapy treatment in the HOPD setting. CMS calculates separate rates for inpatient admissions and ED visits, and does not combine them into a single score. Those patients experiencing both an inpatient admission and ED visit are counted toward the inpatient admission rate. Rather than being an "all-cause" measure, OP-35 only includes inpatient admissions and ED visits for the following 10 conditions – anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia and sepsis. Measure results are attributed to patients

OP-35 is calculated using Medicare claims data, and does not require hospitals to collect and submit data. The measure includes Medicare FFS patients 18 years and older with a diagnosis of any cancer – except leukemia – during the measure performance period. OP-35 excludes leukemia patients because of concerns that hospital visits for leukemia reflect the relative toxicity of the treatment and frequent recurrence of the disease, rather than shortcoming in quality of care.

For the purposes of calculating OP-35, CMS attributes patients to the hospital where they received chemotherapy treatment. If a patient receives treatment at two different hospitals within the 30-day timeframe covered by the measure, then the patient would be attributed to **both** hospitals.

Similar to other hospital admission and readmission measure, OP-35 is adjusted patient clinical factors (i.e., co-morbid conditions and pre-existing conditions) that contribute to the likelihood of hospital visits. However, measure results would not adjusted for the socioeconomic status of patients or communities. Moreover, the measure is not endorsed by the NQF.

<u>Hospital Visits after Outpatient Surgery (OP-36)</u>. Proposed for the CY 2020 OQR program, OP-36 calculates the rate of hospital visits – including inpatient admissions, ED visits and observation stays – occurring in the seven days after "same day" surgeries in an HOPD. In contrast to OP-35, CMS calculates a single rate for OP-36 encompassing all of the hospital visit types listed above. The measure is endorsed by the NQF.

OP-36 is calculated by CMS using Medicare claims data, and includes all patients 65 years and older undergoing a "substantive surgery or procedure" included on Medicare's list of covered ASC procedures. CMS believes the use of the ASC procedure list is appropriate because they want the measure to assess hospital visits for "surgeries that have a low to moderate risk profile and are safe to be performed as same-day surgeries." Moreover, the list is annually reviewed, and includes a public commenting process. The list of covered ASC procedures for 2016 is posted on CMS's <u>website</u> (refer to Addendum AA). CMS excludes patients undergoing eye surgeries because it believes it risk of adverse outcomes is significantly lower than that of other procedures assessed in the measure.

Similar to other hospital admission and readmission measure, OP-36 is adjusted patient clinical factors (i.e., co-morbid conditions and pre-existing conditions) that contribute to

the likelihood of hospital visits. However, measure results would not adjusted for the socioeconomic status of patients or communities.

OAS CAHPS Survey Measures (OP-37a - 37e).

OAS CAHPS Overview. For the CY 2020 OQR program, CMS proposes to adopt five measures derived from the 37-item OAS CAHPS patient experience of care survey. The survey has been under development for several years, and is part of the same family of surveys as the Hospital CAHPS (HCAHPS) that is required for both the hospital inpatient quality reporting (IQR) and hospital VBP programs. However, the OAS CAHPS would be administered only to patients receiving surgeries and certain other procedures in the HOPD setting. In proposing the measure, CMS states that the use of the OAS CAHPS would promote alignment of patient experience measurement across inpatient and outpatient settings, and fill a perceived measurement gap.

On Jan. 1, 2016, CMS initiated a voluntary national reporting program for OAS CAHPS. CMS proposes to require the collection and submission of OAS CAHPS on a quarterly basis, starting with procedures on Jan. 1, 2018. As is the case with HCAHPS, hospitals would be required to use CMS-approved survey vendors to collect and submit survey data. A list of approved vendors is available at <u>http://oaschaps.org</u>.

The AHA has long been supportive of rigorously designed surveys of patient experience of care, including the HCAHPS survey. However, we are concerned that the implementation of OAS CAHPS is premature for a number of reasons. First, the OAS CAHPS survey measures are not endorsed by the NQF, which significantly limits the hospital field's insight into whether the measures portray hospital performance in a fair and accurate manner. Given the significant resources needed to collect the survey, we believe the measures should be NQF endorsed before OAS CAHPS is required of hospitals. Additionally, we are concerned that the CAHPS program already includes multiple overlapping survey tools. The inclusion of yet another survey may lead to confusion among patients about which provider is being assessed, and excessive survey administration burden.

OAS CAHPS Survey Requirements. Hospitals would be required to collect the OAS CAHPS on a random sample of eligible patients on a monthly basis, and submit it to CMS on a quarterly basis. Patients eligible to be included in the sampled patient population would be identified using sets of billing codes:

- **CPT Codes** in the range from 10021 to 69990, which include a variety of procedures done on an outpatient basis. These include colonoscopy, hernia repair and injections for pain management.
- The following G-codes:
 - G0104 Colorectal cancer screening; flexible signmoidoscopy
 - G0105 Colorectal cancer screening; colonoscopy on individual at high risk
 - G0121 Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk

 G0260 – Injection procedure for sacroiliac join; provision of anesthetic, steroid

The OAS CAHPS survey could be administered using three modes – mail-only, telephone-only and "mixed mode" (i.e., mail with telephone follow up for non-respondents). Additional details on these survey modes are available on the OAS CAHPS <u>website</u>. Vendors would be required to give patients the OAS CAHPS survey using the above modes no later than 21 days after the month in which a patient receives the procedure. To count as a "complete survey," the data must be collected within six weeks of when the patient is initially provided the survey. CMS would expect survey vendors to make multiple attempts to reach the patient, unless the patient refuses to complete the survey, or the hospital learns the patient is ineligible for the survey.

Consistent with the HCAHPS survey requirements, hospitals would be required to collect at least 300 completed survey over each 12 month reporting period (i.e., an average of 25 completed surveys per month). Smaller hospitals that cannot collect 300 completed surveys in a 12-month period would be required to collect as many surveys as possible during the time period. However, those hospitals that treat fewer than 60 survey-eligible patients in the year preceding the data collection period would be allowed to request an exemption from OAS CAHPS reporting.

OAS CAHPS Survey Content. Of the 37 items on the OAS CAHPS survey, 24 items are "core" survey questions assessing patient perspectives on care access, communications with providers, experience at the facility and interactions with facility staff. There also are two "global" survey items asking patients to give the facility an overall rating of zero to 10, and to indicate how strongly they would recommend the facility to others. Lastly, there are nine items asking patients to report their own health status and demographic information (e.g., race/ethnicity, education level, language). Responses to these nine items are used to risk adjust hospital performance on the survey measures.

The responses to the "core" survey questions have various rating scales. Some ask patients for one of three possible responses (i.e., yes definitely, yes somewhat or no), while others have only two responses (i.e., yes or no). The global overall rating item asks for a response on a scale of 0 to 10, while the recommendation of facility question has four responses (i.e., definitely yes, probably yes, probably no or definitely "no").

OAS CAHPS Measures. CMS proposes to calculate a total of five measures from OAS CAHPS results – three "composite" survey measures that aggregate the results of several related questions into a single score, and two "global" measures that ask the patient to rate their overall experience at the facility. The measures are:

- Composite:
 - o OP-37a: OAS CAHPS About Facilities and Staff
 - o OP-37b: OAS CAHPS Communication About Procedure
 - OP-37c: OAS CAHPS Preparation for Discharge and Recovery
- Global:
 - OP-37d: OAS CAHPS Overall Rating of Facility

o OP-37e: OAS CAHPS - Recommendation of Facility

To calculate performance on the three composite measures, CMS would determine the proportion of "top box" scores (i.e., proportion of patients answering "Yes" or "Definitely Yes") on individual questions, and average them into a composite. For the two global measures, CMS would calculate the proportions of patients providing high-value responses (i.e., a rating of 9 or 10 on OP-37d, and an answer of "definitely yes" on OP-37e). CMS would adjust the survey scores for patient characteristics. However, CMS does not indicate whether it will adjust survey results for the mode of survey administration.

<u>Extraordinary Circumstances Exception (ECE) Process</u>. In previous rulemaking, CMS adopted an ECE process in which hospital affected by natural disasters and other extraordinary events affecting their ability to report quality data could request an exemption from reporting quality data for a particular time period. Under existing policy, hospitals would have 45 days from the date of the event to request an ECE. CMS proposes to extend this timeframe to 90 days in order to align the OQR's ECE process with that for other hospital quality reporting and pay-for-performance programs.

REMOVAL OF HCAHPS PAIN QUESTIONS FROM VBP SCORES

The AHA is pleased that CMS proposes to exclude the results from three pain management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey in determining hospitals' VBP program scores. We had strongly urged CMS to suspend the pain-related questions in the VBP program while the agency works to address concerns that the questions may create pressure to prescribe opioids. CMS's proposal would start in the FY 2018 program year. CMS will continue to collect and publicly report the results of the HCAHPS pain management questions. However, the agency is field testing alternative pain management questions, which could be incorporated into the HCAHPS survey through future rulemaking.

PROPOSED CHANGES FOR THE CY 2017 ASC PAYMENT SYSTEM

The proposed rule also includes the annual review and update to the ASC list of covered surgical procedures and covered ancillary procedures, as well as updated payment rates.

Updates and Changes to ASC Payment Policy

<u>Updating the ASC Relative Payment Weights for CY 2017</u>. CMS updates the relative payment weights in the ASC payment system each year using the national OPPS relative payment weights (and PFS non-facility practice expense amounts, as applicable) for that same calendar year and uniformly scales the ASC relative payment weights to make them budget neutral. For CY 2017, CMS proposes to use an ASC scaler of 0.9030.

<u>Updating the ASC Conversion Factor</u>. The ACA requires that, beginning in CY 2011, the annual inflation update under the ASC payment system (the Consumer Price Index for All Urban Consumers (CPI-U)) must be reduced by a productivity adjustment. For CY 2017, the CPI-U update is projected to be 1.7 percent. As required by the ACA, this update is reduced by a productivity adjustment, which is projected to be 0.5 percentage point, resulting in a net 1.2 percent update for CY 2017. CMS further proposes to apply a 0.9992 ASC wage index budget-neutrality adjustment in calculating the CY 2017 ASC conversion factor. The net CPI-U update, together with the wage adjustment for budget neutrality, results in a proposed CY 2017 ASC conversion factor of \$44.684. In contrast, the proposed CY 2017 OPPS conversion factor is \$74.909.

ASCs that fail to meet their quality reporting requirements will have their conversion factor update reduced by 2.0 percentage points. The net update for ASCs not meeting quality reporting requirements would be negative 0.8 percent, which, together with the wage adjustment for budget neutrality, results in a proposed reduced CY 2017 ASC conversion factor of \$43.801. By contrast, the reduced OPPS conversion factor is \$73.411.

<u>ASC-covered Surgical Procedures</u>. CMS proposes to add eight surgical procedures to the list of ASC-covered surgical procedures, which are listed in Table 29 of the proposed rule. Three of the eight proposed additions to the list of ASC covered surgical procedures are procedure codes that are proposed for removal from the OPPS inpatient-only list.

<u>Surgical Procedures Designated as Office-based</u>. Office-based procedures are procedures that CMS determines are performed predominantly (more than 50 percent of the time) in physicians' offices. They are paid at the lower of the Medicare PFS non-facility practice expense relative value unit amount or the amount calculated using the ASC standard rate-setting methodology for the procedure.

For CY 2017, CMS proposes to permanently designate one additional covered surgical procedures as an office-based procedure (see Table 26 in the proposed rule). In addition, CMS proposes to retain the temporary office-based status of all eight procedures assigned this designation in the CY 2016 final rule (see Table 27 in the proposed rule). Finally, CMS proposes to assign temporary office-based status to two new CY 2017 codes for ASC-covered surgical procedures (see Table 28 in the proposed rule).

<u>ASC-covered Surgical Procedures Designated as Device-intensive</u>. CMS currently applies a modified payment methodology for ASC-covered procedures eligible for payment according to the device-intensive procedure payment methodology. That policy is in place to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in these procedures. In CY 2015, CMS implemented a comprehensive APC policy under the OPPS under which comprehensive APCs replaced most of the then-current device-dependent APCs. CMS did not, however, implement comprehensive APCs in ASCs because the ASC payment system was not configured to accommodate this type of payment. CMS proposes to continue using the standard OPPS APC rate-setting methodology to calculate the device offset percentage for purposes of identifying device-intensive procedures and to calculate payment rates for device-intensive procedures assigned to comprehensive APCs. CMS defines an ASC device-intensive procedure as one that is assigned to any APC with a device offset percentage greater than 40 percent based on the standard OPPS APC rate setting methodology.

However, CMS believes that it is no longer appropriate to designate ASC deviceintensive procedures based on APC assignment, because APC groupings of clinically similar procedures do not necessarily factor in device cost similarity. Therefore, for 2017, CMS proposes that a procedure with a HCPCS code-level device offset of greater than 40 percent of the APC costs, when calculated according to the standard OPPS APC rate setting methodology, would be designated as an ASC device-intensive procedure.

For 2017, CMS proposes to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive payment methodology, consistent with its proposed revise definition of device-intensive procedures. The list of these procedures and related information is included in Addendum AA on CMS's ASC website.

ASC Quality Reporting (ASCQR) Program

The ACA required CMS to establish a program under which ASCs must report data on the quality of care delivered in order to receive the full annual update to the ASC payment rate. ASCs failing to report the data will incur a reduction in their annual payment update factor of 2.0 percentage points.

For the CY 2020 ASCQR program, CMS proposes the same five OAS CAHPS measures that it proposes for the OQR program. Please see the OQR section of this advisory for additional information about the OAS CAHPS measures and reporting requirements. In addition, CMS proposes two other measures for the ASCQR program, both of which would be chart-abstracted and submitted using CMS's web-based tool on QualityNet:

- ASC-13 Normothermia outcome, which assesses the percentage of patients undergoing surgical procedures under general or neuraxial anesthesia whose body temperatures are normal within 15 minutes of arrival in post-anesthesia care units; and
- **ASC-14 Unplanned victrectomy**, which assesses the percentage of cataract surgery patients who undergo unplanned anterior victrectomies (i.e., unplanned repairs of the mainly liquid portion of the eye).

A list of finalized and proposed ASCQR measures can be found in Appendix B of this advisory.

PROPOSED CHANGES TO THE MEDICARE AND MEDICAID ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM

In the rule, CMS proposes: (1) changes to the EHR Incentive Program objectives and measures for EHs and CAHs for Modified Stage 2 and Stage 3, starting with the EHR reporting periods in CY 2017; (2) changes to the EHR reporting period in CY 2016 for EHs, CAHs and Eps; (3) to revise the reporting period for EHs, CAHs and EPs that are new program participants in CY 2017; (4) to clarify the policy on measure calculations for actions outside the EHR reporting period; and (5) a one-time significant hardship exception from the 2018 payment adjustment for new EPs in the EHR Incentive Program in CY 2017 that are transitioning to the Merit-Based Incentive Payment System (MIPS) in CY 2017.

The proposals to remove objectives and measures or change measure thresholds would not apply to EHs and CAHs attesting under the Medicaid EHR Incentive Program. CMS states its concern that states would incur additional cost and time burdens in updating their technology and reporting systems within a short period of time if the proposed changes to the objectives and measures were applicable to the Medicaid EHR Incentive Program.

Proposed Removal of Medicare EHR Incentive Program Objectives

<u>Removal of Objectives</u>. For Modified Stage 2 in CY 2017 and Stage 3 in CY 2017 and 2018, CMS proposes to remove the Clinical Decision Support (CDS) and Computerized Provider Order Entry (CPOE) objectives and associated measures. CMS states that 99 percent of EHs and CAHs attested "yes" to meeting these measures in 2015 and, therefore, the objective and measures are topped out and no longer useful in gauging performance. CMS also states that the CPOE performance has topped out, as performance for the objective and measures is more than 90 percent.

Proposed Changes to Medicare Modified Stage 2 Measures

<u>Revision of Measure Thresholds</u>. For the Modified Stage 2 Patient Electronic Access objective, CMS proposes that at least one unique patient (or patient-authorized representative) discharged from the EH or CAH inpatient or ED (POS 21 or 23) views, downloads or transmits to a third party his or her health information during the EHR reporting period. The proposed threshold is lower than the 5 percent threshold in the Modified Stage 2 final rule. **The AHA is pleased to see CMS propose a less stringent requirement for 2017.**

CMS proposes to continue to offer a measure exclusion for any EH or CAH in a county where 50 percent of more of the housing units lack 4Mbps broadband availability on the first day of the EHR reporting period.

Appendix C lists the proposed Modified Stage 2 objectives and measures for CY 2017.

Proposed Changes to Medicare Stage 3 Measures

<u>Revision of Measure Thresholds</u>. For CY 2017 and 2018, CMS proposes to modify seven measure thresholds included in Stage 3. The AHA appreciates this proposal to reduce the Stage 3 reporting requirements for EHs and CAHs.

Patient Electronic Access Objective

Patient Access Measure: CMS proposes that, for more than 50 percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23): (1) the patient (or the patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application program interface (APIs) in the provider's certified EHR. The proposed threshold is lower than the 80 percent threshold in the Stage 3 final rule.

Patient-specific Education Measure: CMS proposes that for more than 10 percent of unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, the EH or CAH must use clinically relevant information from the certified EHR to identify patient-specific educational resources and provide electronic access to those materials. The proposed threshold is lower than the 35 percent threshold in the Stage 3 final rule.

Coordination of Care through Patient Engagement Objective

View/Download/Transmit Measure: CMS proposes that at least one unique patient (or patient-authorized representative) who is discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider and one of the following: (1) view, download or transmit to a third party their health information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified EHR; or (3) a combination of (1) and (2). The proposed threshold is lower than the 10 percent threshold in the Stage 3 final rule.

Secure Messaging Measure: CMS proposes that for more than 5 percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of certified EHR to the patient (or the patient-authorized representative), or sent in response to a secure message sent by the patient (or the patient-authorized representative). The proposed threshold is lower than the 25 percent threshold in the Stage 3 final rule.

Health Information Exchange Objective

Patient Care Record Exchange Measure: CMS proposes that for more than 10 percent of transitions of care and referrals, the EH or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using certified EHR and (2) electronically exchanges the summary of care record. The proposed threshold is lower than the 50 percent threshold in the Stage 3 final rule.

Request/Accept Patient Care Record Measure: CMS proposes that for more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH incorporates into the patient's EHR an electronic summary of care document. The proposed threshold is lower than the 40 percent threshold in the Stage 3 final rule.

Clinical Information Reconciliation Measure: CMS proposes that for more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH performs a clinical information reconciliation for three clinical information sets: (1) Medications, including a review of the name, dosage, frequency, and route of each medication; (2) Medication allergies; and (3) Current Problem list, including the patient's current and active diagnoses. The proposed threshold is lower than the 80 percent threshold in the Stage 3 final rule.

The AHA appreciates the proposal to reduce seven Stage 3 threshold reporting requirements for EHs and CAHs for CY 2017 and 2018.

Measure Exclusions

CMS proposes to continue to offer an exclusion for each of the seven measures for any EH or CAH in a county where 50 percent of more of the housing units lack 4Mbps broadband availability on the first day of the EHR reporting period. For the Request/Accept Patient Care Record Measure, CMS also proposes an exclusion for any EH or CAH with fewer than 100 total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient.

Appendix D lists the proposed Stage 3 objectives and measures for CYs 2017 and 2018.

Medicare Stage 3 Measures That Remain Unchanged

For CYs 2017 and 2018, CMS proposes to retain several measure thresholds included in Stage 3.

Protect Electronic Health Information Objective.

Security Risk Analysis Measure: CMS does not propose a change in the measure requiring EHs and CAHs to conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the EH's or CAH's risk management process.

Electronic Prescribing Objective.

e-Prescribing Measure: CMS does not propose a change in the measure requiring that more than 25 percent of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR.

Coordination of Care through Patient Engagement Objective.

Patient Generated Health Data Measure: CMS does not propose a change in the measure requiring patient-generated data or that data from a non-clinical setting is incorporated into the certified EHR for more than 5 percent of all unique patients.

The AHA is disappointed that CMS proposes to retain several unrealistic Stage 3 requirements, such as the required use of APIs to connect any app of the patient's choice to the EHR in support of patient engagement and coordination of care through patient engagement objectives. The AHA also is disappointed that CMS did not propose revisions to additional Stage 3 measure thresholds, specifically e-prescribing and patient-generated health data.

<u>Revision of Public Health and Clinical Data Registry Measures Reported</u>. To meet the Public Health and Clinical Data Registry Reporting objective, for CYs 2017 and 2018, CMS proposes that the EH or CAH attest to active engagement with any three public health and clinical data registry reporting options from the six available. The proposed threshold is a lower than the requirement to attest to active engagement with four public health and clinical data registry reporting options in the Stage 3 final rule.

Proposed Change to the CY 2016 Reporting Period

Revise the CY 2016 Reporting Period. CMS proposes to change the EHR reporting period for 2016 from a full year to any 90 days for all EHs, CAHs and EPs. In connection with this proposal, CMS also proposes a reporting period of any 90 days for electronic clinical quality measures (eCQMs) in 2016 for all EHs, CAHs and EPs. eCQMs may be reported by attestation or electronically reported. CMS states that eCQM data submitted via attestation can be submitted for a different 90 day period than the EHR reporting period for meaningful use objectives and measures. **The AHA is pleased by the proposal for a 90-day reporting period for 2016.**

<u>Revise the Reporting Period for New EHs, CAHs and EP in CY 2017</u>. CMS proposes that EHs and EPs new to the EHR Incentive Program in CY 2017 that seek to avoid the 2018 payment adjustment or any CAH new to the EHR Incentive Program in CY2017 that seeks to avoid the 2017 payment adjustment attest to Modified Stage 2 (rather than Stage 3) objectives and measures.

CMS states that it is not it is not technically feasible for EHs, CAHs and EPs that have not successfully demonstrated meaningful use in a prior year (new participants) to attest

to the Stage 3 objectives and measures in CY 2017 in the EHR Incentive Program Registration and Attestation System. The agency adds that in early 2018, returning EHs and CAHs will be transitioned to other reporting systems to attest for CY 2017. CMS also states that providers using 2014 Edition, 2015 Edition, or any combination of 2014 and 2015 Edition certified EHR technology in 2017 would have the necessary technical capabilities to attest to the Modified Stage 2 objectives and measures.

<u>Clarify Measure Calculations Outside of the EHR Reporting Period</u>. CMS proposes actions included in the numerator for meaningful use measures must occur within the EHR reporting period if that period is a full calendar year. If the reporting period is less than a full calendar year, the actions must occur within the calendar year in which the EHR reporting period occurs. CMS states that the proposal is intended to address the open-ended timeframe implied in FAQ 8231, which states that actions may fall outside of the EHR reporting period but must take place no earlier than the start of the reporting period and no later than the date of attestation.

Significant Hardship Exceptions for New EPs Transitioning to MIPS in CY 2017.

CMS proposes to allow EPs to apply for a significant hardship exception from the 2018 payment adjustment if they have not successfully demonstrated meaningful use in a prior year, intend to attest to meaningful use for an EHR reporting period in CY 2017 by Oct. 1, 2017 to avoid the 2018 payment adjustment, and intend to transition to MIPS and report on measures specified for the advancing care information performance category under the MIPS in CY 2017. CMS adds that this proposed significant hardship exception is based on 2017 as the first performance period for MIPS per the MACRA proposed rule. If CMS decides to not finalize that proposal and instead adopts a different performance period for the MIPS that does not coincide with the final year for EPs to attest to meaningful use, CMS may determine that this significant hardship exception is not necessary.

PROPOSED CHANGES TO THE MEDICARE REQUIREMENTS FOR TRANSPLANT CENTERS AND ORGAN PROCUREMENT ORGANIZATIONS

Observed to Expected Rates

In 2007, CMS established Conditions of Participation (CoPs) for solid organ transplant programs. Among the outcome requirements described in the CoPs, a transplant program will be noncompliant with patient and graft survival standards if it crosses three specific thresholds: (1) the observed to expected (O/E) ratio of patient deaths and graft failures exceeds 1.5; (2) the results are statistically significant (p<.05); and (3) the results are numerically meaningful (if the number of observed events minus the expected number surpasses 3).

CMS notes that the expected number of events is based on the national average. Given that national performance has improved over time, the agency believes that it has become more difficult for transplant centers to meet the first of these three thresholds. CMS is concerned that transplant centers are discouraged from using certain organs that could adversely affect their outcomes metrics. Therefore, CMS proposes to change the threshold from 1.5 to 1.85 for all organ types. The agency hopes that, by "restoring rough parity to 2007 graft failure rates," transplant centers will be encouraged "to use more of the increasing number of viable organs."

Mitigating Factors Review: Timeframes for Notification/Data Submission

The CoPs allow CMS to consider select "mitigating factors" in some circumstances when approving or reapproving a transplant center. Currently, transplant centers are required to notify CMS of the intent to request mitigating factors approval within 10 days after a formal written notice of a condition-level deficiency. In addition, transplant centers have 120 days to submit to CMS the relevant materials for consideration of mitigating factors. CMS proposes to extend the notification period from 10 days to 14 calendar days. CMS also would clarify that the timeframe to submit mitigating factors materials is 120 <u>calendar</u> days. Currently, the regulation does not specify whether the timeframe is calendar or business days.

Systems Improvement Agreements (SIA)

The agency would revise regulations related to SIA. Specifically, CMS proposes to clarify that a signed SIA remains in place even if a subsequent report by the Scientific Registry of Transplant Recipients (SRTR) signifies that the transplant program has met the CoPs. However, CMS could shorten the SIA timeframe or allow other modifications.

Organ Procurement Organizations (OPO)

CMS also proposes several changes to the requirements for OPOs. Among the changes, CMS would reduce the amount of paper documentation that must be sent to a receiving transplant center. CMS believes that the required data can be accessed electronically. Paper documentation would still be needed for blood typing and infectious disease information.

NEXT STEPS

The AHA strongly encourages members to submit comments to CMS outlining how the agency's proposals, particularly the proposed policies for implementing the site-neutral payment cuts under Section 603 of the BiBA will affect their facilities. Look for a model comment letter from the AHA in August that you can customize with your own particular situations. You can learn more about the CY 2017 OPPS/ASC proposed rule provisions by viewing a recording of the July 19 AHA members-only webinar, "The CY 2017 OPPS/ASC Payment System Proposed Rule: What You Need to Know." To download the recording of the webinar, click here <u>www.aha.org/oppswebinar</u>.

Comments are due to CMS by Sept. 6 and may be submitted electronically at <u>http://www.regulations.gov</u>. Follow the instructions for "Comment or Submission." Attachments can be in Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word. CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.
Via regular mail: Centers for Medicare & Medicaid Services Dept. of Health and Human Services Attention: CMS-1656-P P.O. Box 8013 Baltimore, MD 21244-1850

Via overnight or express mail:

Centers for Medicare & Medicaid Services Dept. of Health and Human Services Attention: CMS-1656-P Mailstop: C4-26-05 7500 Security Boulevard Baltimore, MD 21244-1850

FURTHER QUESTIONS

Please contact Roslyne Schulman, director of policy, at <u>rschulman@aha.org</u> for more information about the proposed rule.

Appendix A: Finalized and Proposed Hospital OQR Program Measures, CY 2016 – 2020 Payment Determination

| Measure | CY 2016 | CY 2017 | CY 2018 | CY 2019 | CY 2020 | |
|---|------------------------|----------------|----------------|----------------|--------------------------|--|
| Cancer Care (Chart-abstracted, reported by hospitals via QualityNet web-based tool) | | | | | | |
| OP-33: External beam radiotherapy | | | Х | X | Х | |
| (EBRT) for bone metastases | | | | | | |
| Cardiac Care (Chart-abstracted, collec | ted by hospita | ls via CART | / vendor, sul | bmitted via Q | ualityNet [#]) | |
| OP-1: Median time to fibrinolysis | Х | Х | Х | Х | X X | |
| OP-2: Fibrinolytic therapy received | Х | Х | Х | Х | Х | |
| within 30 minutes | | | | | | |
| OP-3: Median time to transfer to | Х | Х | Х | Х | Х | |
| another facility for acute coronary | | | | | | |
| intervention | | | | | | |
| OP-4: Aspirin at arrival | Х | Х | X | Х | X | |
| OP-5: Median time to electrocardiogram | Х | Х | Х | Х | Х | |
| (ECG) | | | | | | |
| Cataract Surgery (Chart-abstracted, re | | | | | | |
| OP-31: Cataracts—Improvement in | Suspended ² | Voluntary | Voluntary | Voluntary | Voluntary | |
| patient's visual function within 90 Days | | reporting | reporting | reporting | reporting | |
| following cataract Surgery | | | | | | |
| ED (Chart-abstracted. OP-18, OP-19 an | | cted by hosp | oitals via CAF | RT / vendor. # | OP-22 | |
| reported via QualityNet web-based too | | | | | | |
| OP-18: Median time from ED arrival to | Х | Х | Х | Х | Х | |
| ED departure for discharged ED | | | | | | |
| patients | X | X | X | X | X | |
| OP-20: Door to diagnostic evaluation by | Х | Х | Х | Х | Х | |
| a qualified medical professional | X | X | X | X | X | |
| OP-22: ED Left without being seen | X | X | X | X | Х | |
| Endoscopy (Chart-abstracted, reported | | | | | X | |
| OP-29: Appropriate follow-up interval | Х | Х | Х | Х | Х | |
| for normal colonoscopy in average risk | | | | | | |
| patients | Х | Х | Х | Х | Х | |
| OP-30: Colonoscopy interval for | ^ | ^ | ^ | ^ | ^ | |
| patients with a history of adenomatous | | | | | | |
| polyps—Avoidance of inappropriate use Healthcare Associated Infections (Coll | lasted by been | itala submi | ttod via Natio | nal Haalthaa | ra Safatu | |
| Network) | ected by nosp | ilais, subiiii | | nai neallica | le Salely | |
| OP-27: Influenza vaccination coverage | Х | Х | Х | Х | Х | |
| among health care personnel (HCP) | | | | | | |
| Hospital Visit Rates (Claims-based, ca | Iculated by CN | IS) | | | | |
| OP-32: Facility 7-Day risk-standardized | | | Х | Х | Х | |
| hospital visit rate after outpatient | | | | | | |
| colonoscopy | | | | | | |
| OP-35: Admissions and ED visits for | | | | | X ¹ | |
| patients receiving outpatient | | | | | | |
| chemotherapy | | | | | | |

| Measure | CY 2016 | CY 2017 | CY 2018 | CY 2019 | CY 2020 |
|---|---------------------|---------------------|--------------|----------------|----------------|
| OP-36: Hospital visits after outpatient | | | | | X ¹ |
| surgery | | | | | |
| | | | | | |
| Imaging Efficiency (Claims-based, cal | culated by CM | | r | r | 1 |
| OP-8: MRI lumbar spine for low back | Х | X | Х | Х | Х |
| pain | | | | | |
| OP-9: Mammography follow-up rates | X | X X | X | X | X |
| OP-10: Abdomen CT – Use of contrast | Х | X | Х | Х | Х |
| material | | | | | |
| OP-11: Thorax CT – Use of contrast | X | Х | Х | Х | Х |
| material | Х | Х | X | X | Х |
| OP-13: Cardiac imaging for | × | × | × | × | × |
| preoperative risk assessment for non- cardiac low risk surgery | | | | | |
| OP-14: Simultaneous use of brain CT | X | Х | Х | Х | Х |
| and sinus CT | ^ | ^ | ^ | ^ | ^ |
| Pain Management (Chart-abstracted, c | ollected by by | l Senitals via (| CART or venc | lor submitte | l via |
| QualityNet [#]) | onected by no | | | ior, submitted | ı via |
| OP-21: ED- Median time to pain | X | X | X | X | X |
| management for long bone fracture | | | | | ~ |
| Patient Experience of Care (Based on | OAS CAHPS* | * survev coll | ected and su | bmitted by su | irvev |
| vendors) | | | | | , |
| OP-37a: OAS CAHPS – About facilities | | | | | X ¹ |
| and staff | | | | | |
| OP-37b: OAS CAHPS – | | | | | X ¹ |
| Communication about procedure | | | | | |
| OP-37c: OAS CAHPS – Preparation for | | | | | X ¹ |
| discharge and recovery | | | | | |
| OP-37d: OAS CAHPS – Overall rating | | | | | X ¹ |
| of facility | | | | | |
| OP-37e: OAS CAHPS – | | | | | X ¹ |
| Recommendation of facility | | | | | |
| Stroke (Chart-abstracted, reported by | | | | | |
| OP-23: Head CT scan results for acute | Х | X | Х | Х | Х |
| ischemic stroke or hemorrhagic stroke | | | | | |
| who received head CT scan | | | | | |
| interpretation within 45 minutes of | | | | | |
| arrival | | | | | |
| Surgery (Chart-abstracted, collected b | | a CARI or Vo | endor, submi | tted via Quali | tynet") |
| OP-6: Timing of antibiotic prophylaxis | X | | | | |
| OP-7: Prophylactic antibiotic selection | Х | | | | |
| for surgical patients | nitale vie Orie | lityNot woh | hasod tool) | | |
| Structural Measure (Submitted by hos OP-12: The ability for providers with | Vitais via Qua X | X | X | X | Х |
| health information technology (HIT) to | ^ | ^ | ^ | ^ | ^ |
| receive laboratory data electronically | | | | | |
| directly into their qualified/certified EHR | | | | | |
| System as discrete searchable data | | | | | |
| Oysicin as usurele searchable uala | l | L | | | |

| Measure | CY 2016 | CY 2017 | CY 2018 | CY 2019 | CY 2020 |
|---|---------|---------|---------|---------|---------|
| OP-17: Tracking clinical results between visits | Х | Х | Х | Х | Х |
| OP-25: Safe Surgery Checklist use | Х | Х | Х | Х | Х |
| OP-26: Hospital outpatient volume data on selected outpatient surgical procedures | Х | Х | Х | Х | Х |

CART is the CMS Abstraction and Reporting Tool. Hospitals may also elect to have measure collection and submission performed by third-party vendors.

** OAS CAHPS is the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems

¹ Proposed in the CY 2017 OPPS proposed rule

²Per CMS announcement on April 2, 2014.

Appendix B: Finalized and Proposed ASCQR Program Measures, CY 2016 – 2020 Payment Determination

| Measure | CY 2016 | CY 2017 | CY 2018 | CY 2019 | CY 2020 |
|--|----------------|--------------|-------------|--------------|----------------|
| Reported by ASCs through the inclusion | | | | | |
| and subsequently calculated by CMS | | | | | , |
| ASC-1: Patient burns | Х | Х | Х | Х | Х |
| ASC-2: Patient falls | Х | Х | X X | Х | X X |
| ASC-3: Wrong site, wrong side, wrong | Х | Х | Х | Х | Х |
| patient, wrong procedure, wrong | | | | | |
| implant | | | | | |
| ASC-4: Hospital transfer / admission | Х | Х | Х | Х | Х |
| ASC-5: Prophylactic intravenous | Х | Х | Х | Х | Х |
| antibiotic timing | | | | | |
| Cataract Surgery (Chart-abstracted, s | | | | | |
| ASC-11: Cataracts—Improvement in | Suspended | Voluntary | Voluntary | Voluntary | Voluntary |
| patient's visual function within 90 Days | 2 | Reporting | Reporting | Reporting | Reporting |
| following cataract surgery | | | | | |
| ASC-14: Unplanned anterior vitrectomy | | | | | X ¹ |
| Complications from anesthesia (Char | t-abstracted, | submitted b | y ASCs via | QualityNet w | eb-based |
| tool) | T | | I | | 4 |
| ASC-13: Normothermia outcome | | | | | X ¹ |
| Endoscopy (Chart-abstracted, submit | | | | | |
| ASC-9: Appropriate Follow-Up Interval | X | X | X | Х | Х |
| for Normal Colonoscopy in Average | | | | | |
| Risk Patients | X | | X | | |
| ASC-10: Colonoscopy Interval for | X | Х | Х | Х | Х |
| Patients with a History of Adenomatous | | | | | |
| Polyps—Avoidance of Inappropriate | | | | | |
| Use | ested and aut | mitted by A | | | |
| Healthcare Associated Infection (Colle ASC-8: Influenza Vaccination | | X | | X | X |
| Coverage Among Healthcare | ^ | ^ | ^ | ^ | ^ |
| Personnel | | | | | |
| Hospital Visit Rates (Claims-based, ca | alculated by C | CMS) | | | |
| ASC-12: Facility 7-Day risk- | | | Х | X | X |
| standardized hospital visit rate after | | | ~ | Λ | Х |
| outpatient colonoscopy | | | | | |
| Patient Experience of Care (Based on | OAS CAHPS | ** survev co | llected and | submitted by | v survev |
| vendors) | | ····· | | | , |
| ASC-15a: OAS CAHPS – About | | | | | X ¹ |
| facilities and staff | | | | | |
| ASC-15b: OAS CAHPS – | | | | | X ¹ |
| Communication about procedure | | | | | |
| ASC-15c: OAS CAHPS – Preparation | | | | | X ¹ |
| for discharge and recovery | | | | | |
| ASC-15d: OAS CAHPS - Overall rating | | | | | X ¹ |
| of facility | | | | | |

| Measure | CY 2016 | CY 2017 | CY 2018 | CY 2019 | CY 2020 | |
|---|---------|---------|---------|---------|----------------|--|
| ASC-15e: OAS CAHPS – | | | | | X ¹ | |
| Recommendation of facility | | | | | | |
| Structural Measures (Collected and submitted by ASCs via QualityNet web-based tool) | | | | | | |
| ASC-6: Safe Surgery Checklist Use | Х | Х | Х | Х | Х | |
| ASC-7: ASC Facility Procedural | Х | Х | Х | Х | Х | |
| Volumes on Selected ASC Procedures | | | | | | |

** OAS CAHPS is the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems ¹ Proposed in CY 2017 Outpatient PPS Proposed Rule ² Per CMS announcement on April 2, 2014.

Appendix C: Proposed Medicare EHR Incentive Program Modified Stage 2 Objectives and Measures in CY 2017

| Modified Stage 2 Objective | Current Modified Stage 2 Measures | Proposed Change to Modified Stage 2 |
|--|--|---|
| Protect electronic health information | Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of electronic protected health information created or maintained in Certified EHR Technology in accordance with requirements in 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EH's or CAH's risk management process. | No change. |
| Clinical decision support | Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EH's or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. | Proposed removal of the objective and measure |
| | Measure 2: The EH or CAH has enabled and implemented the functionality for drug-drug and drug- allergy interaction checks for the entire EHR reporting period. | |
| Computerized Provider Order Entry (CPOE) | Measure 1: More than 60 percent of medication orders created by authorized providers of the EH's or CAH's inpatient or ED place of service ((POS) 21 or 23)) during the EHR reporting period are recorded | Proposed removal of the objective and measure |

| Modified Stage 2 Objective | Current Modified Stage 2 Measures | Proposed Change to Modified Stage 2 |
|-----------------------------------|--|--|
| | using CPOE. Measure 2: More than 30 percent of laboratory orders created by authorized providers of the EH's or CAH's inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. | |
| | Measure 3: More than 30 percent of radiology orders created by authorized providers of the EH's or CAH's inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. | |
| e-Prescribing | Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology. | No change. |
| Health information exchange | Measure: The EH or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses Certified EHR Technology to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals. | No change. |
| Patient-specific education | Measure: More than 10 percent of all unique patients admitted to the EH's or CAH's inpatient or ED (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology. | No change. |

| Modified Stage 2 Objective | Current Modified Stage 2 Measures | Proposed Change to Modified Stage 2 |
|---|---|--|
| Medication reconciliation | Measure: The EH or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the EH's or CAH's inpatient or ED (POS 21 or 23). | No change. |
| Patient electronic access (view, download and transmit) | Measure 1: More than 50 percent of all patients who are discharged from the inpatient or ED (POS 21 or 23) of an EH or CAH are provided timely access to view online, download, and transmit to a third party their health information. | No change to objective. |
| | Measure 2: More than 5 percent of unique patients discharged from the inpatient or ED (POS 21 or 23) of an EH or CAH (or patient-authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period. | Measure 2 - View/Download/Transmit Measure: At least 1 patient (or patient authorized representative) who is discharged from the inpatient or ED (POS 21 or 23) of an eligible hospital or CAH during the EHR reporting period views, downloads or transmits to a third party his or her health information during the EHR reporting period |
| Public health EHs and CAHs must report on three of the four measure options. | Immunization Registry Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system. Syndromic Surveillance Reporting Measure: The EH or CAH is in active | No change. |
| | engagement with a public health agency to submit syndromic surveillance data from an | |

| Modified Stage 2 Objective | Current Modified Stage 2 Measures | Proposed Change to Modified Stage 2 |
|-------------------------------|---|--|
| | emergency or urgent care department for EHs and CAHs (POS 23). | |
| | Specialized Registry Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit data to a specialized registry. | |
| | Electronic Reportable Laboratory Result Reporting Measure: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. | |

Appendix D: Proposed Medicare EHR Incentive Program Stage 3 Objectives and Measures

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|---|---|
| 1. Protect electronic health information: Protect electronic protected health information (ePHI) created or maintained by the certified electronic health record technology (certified EHR) through the implementation of appropriate technical, administrative, and physical safeguards. | Measure: Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR) in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the EH's or CAH's risk management process. | No change. |
| 2. Electronic prescribing: Eligible hospitals (EHs) and critical access hospitals (CAHs) must generate and transmit permissible discharge prescriptions electronically (eRx). | More than 25 percent of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR. | No change. |
| 3. Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high- priority health conditions. | Measure 1: Implement five clinical decision support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. Measure 2: Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. | Proposed removal of the objective and measure |

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|---|---|
| 4. Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory, and diagnostic imaging orders. | Measure 1: CPOE for medication - More than 60 percent of medication orders created by authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. | Proposed removal of the objective and measure |
| | Measure 2: CPOE for labs - More than 60 percent of laboratory orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. | |
| | Measure 3: CPOE for diagnostic imaging – More than 60 percent of diagnostic imaging orders created by the authorized providers of the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period are recorded using CPOE. | |
| 5. Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources. | Measure 1: For more than 80 percent of unique patients, either: (i) the patient (or patient- authorized representative) is provided timely access to view online, download, and transmit their health information - and (ii) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's certified EHR. | No change to objective. Specified name for measures- Patient Access Measure: For more than 50 percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21or 23): (1) the patient (or the patient- authorized representative) is provided timely access to view online, download, and transmit his or her health information; and (2) the provider ensures the patient's health information is available |

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|---|--|
| | Measure 2: Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients. | for the patient (or patient- authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the APIs in the provider's certified EHR. |
| | | Patient-Specific Education Measure: The EH or CAH must use clinically relevant information from the certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 10 percent of unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period. |
| 6. Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives. EH and CAH must attest/report the numerators/denomin ators for all three measures and must meet thresholds for two out of three measures. | Measure 1: More than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or ED (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. Measure to be met by patient is one of the following (i) view, download, or transmit to a third parity their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to | No change to objective. Specified name for measures- View/Download/Transmit Measure: At least one unique patient (or patient- authorized representative) who is discharged from the EH or CAH inpatient or ED (POS 21 or 23) actively engage with the EHR made accessible by the provider and one of the following: (1) view, download or transmit to a third party their health |

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|--|---|
| | the API in the provider's certified a combination of (i) and (ii). | information; or (2) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified EHR; or (3) a combination of (1) and (2). |
| | Measure 2: For more than 25 percent of all unique patients or patient's authorized representative discharged from EH or CAH inpatient or ED (POS 21 or 23), certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient. | Secure Messaging Measure: For more than five percent of all unique patients discharged from the EH or CAH inpatient or ED (POS 21 or 23) during the EHR reporting period, a secure message was sent using the electronic messaging function of certified EHR to the patient (or the patient-authorized representative), or sent in response to a secure message sent by the patient (or the patient- authorized representative. |
| | Measure 3: Patient generated data or data from a non-clinical setting is incorporated into the certified EHR for more than five percent of all unique patients. | Patient Generated Health Data Measure: No Change |
| 7. Health information exchange: provide a summary of care record when transitioning or referring their patient | Measure 1: For more than 50 percent of transitions of care and referrals, a summary of care record is created and sent electronically. | No change to objective. Specified name for measures- Patient Care Record Exchange Measure: For more than 10 percent of transitions |

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|--|--|
| to another setting of care, or retrieve a summary of care record upon the first patient encounter with a new patient. EH/CAH must attest/report the numerators/denomin ators for all three measures. Must meet threshold on two of three measures. | Measure 2: For more than 40 | of care and referrals, the EH or CAH that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using certified EHR and (2) electronically exchanges the summary of care record. Request/Accept Patient |
| | percent of transitions and referrals received and patient encounters in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system. | Care Record Measure: For more than 10 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH incorporates into the patient's EHR an electronic summary of care document. |
| | Measure 3: For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH, CAH or EP performs a clinical information reconciliation that includes medications, medication allergy, and current problem list. | Clinical Information Reconciliation Measure: For more than 50 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH or CAH performs a clinical information reconciliation for three clinical information sets: medications, medication allergies; and current problem list. |

| Stage 3 Objective | Current Stage 3 Measures | Proposed Change for Stage 3 |
|---|---|--|
| 8. Public health and clinical data registry reporting: EH or CAH is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data in a meaningful way using certified EHR, except where prohibited and in accordance with applicable law. | Immunization Registry Reporting. The EH or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS). Syndromic Surveillance Reporting. The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. | No change. Change in the number of measures reported: EHs and CAHs report to three of the registries or claim exclusions. The registry measures may be counted more than once if multiple registries are supported. |
| | Case Reporting. The EH or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. | |
| | Public Health Registry Reporting. The EH or CAH is in active engagement with a public health agency to submit data to public health registries. | |
| | Clinical Data Registry Reporting. The EH or CAH is in active engagement to submit data to a clinical data registry. | |
| | Electronic Reportable Lab Result Reporting. The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results. | |